D. D. N. J., F. D. C. 4881–4920 Issued January 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4881–4920

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings which were terminated with the entry of default or consent decrees of condemnation and (2) injunction proceedings terminated with the entry of a consent decree of injunction. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the injunction proceedings are against the *individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 11, 1957.*

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*For omission of, or unsatisfactory, ingredients statements, see No. 4890; failure to bear a label containing an accurate statement of the quantity of the contents, No. 4890; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4890.

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4881–4920

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance; Section 501 (a) (2), the article had been prepared and packed under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from, and its quality fell below, the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality and purity fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4881. **Hormonex.** (F. D. C. No. 38280. S. No. 30–185 M.)

QUANTITY: 233 1-oz. btls. at St. Louis, Mo.

SHIPPED: 6–15–55, from Paris, Tenn., by Golden Peacock, Inc.

LABEL IN PART: (Btl.) "Hormonex Beauty Serum Use only 8 drops daily Mitchum Distributors Fifth Ave. New York Just 8 drops of Hormonex Beauty Serum gives your skin the maximum daily allotment of natural female hormones. Use dropper top to measure 8 drops into the palm of one hand. Spread over the face and throat with the fingertips of other hand. Contains 150,000 I. U. Natural estrogenic hormones."

LIBELED: 8–15–55, E. Dist. Mo.

CHARGE: 502 (j)—the article, when shipped, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions for use, which appeared on the bottle label, provided for the daily application of approxi-

mately 1,500 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which could cause injury to health.

DISPOSITION: 9–23–55. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4882. Broiler Pre-Mix. (F. D. C. No. 38248. S. No. 16–247 M.)

QUANTITY: 10 50-lb. bags at Seattle, Wash.

SHIPPED: 5–27–55, from Pasadena, Calif., by Ray Ewing Co.

LABEL IN PART: (Bag) "A Ray Ewing Custom Mix * * * Broiler Pre-Mix Guaranteed Potencies * * * Nicarbazin, Grams 90.80 Per Pound."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 7 percent of the declared amount of nicarbazin.

LIBELED: 7–27–55, W. Dist. Wash.

CHARGE: 502 (a)—the label statement "Guaranteed Potencies * * * Nicarbazin, Grams 90.80 Per Pound" was false and misleading; 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11–30–55. Default—destruction.

4883. Serpina tablets. (F. D. C. No. 38244. S. No. 24–721 M.)

QUANTITY: 1 unlabeled drum containing 5,000 tablets at Seattle, Wash.

SHIPPED: 3–30–55, from Bombay, India, by Himalaya Drug Co.

RESULTS OF INVESTIGATION: The article was shipped from India in a bulk container labeled in part "Serpina Each tablet contains 4 mg. of the total alkaloids of Rauwolfia serpentina (Benth)."

LIBELED: 7–26–55, W. Dist. Wash.

CHARGE: 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 11–30–55. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

4884. Halazone tablets and Dramamine tablets. (F. D. C. No. 38184. S. Nos. 30–203/4 M.)

QUANTITY: 59 btls. containing 1,000 tablets of *Dramamine*, and 1,100 cases, 300 100-tablet btls. each, of *halazone* at Memphis, Tenn.

SHIPPED: The articles were shipped in interstate commerce to Memphis, Tenn.; however, the name of the shipper and the date of shipment are unknown.

LABEL IN PART: (Btl.) "1,000 Tablets * * * Dramamine Brand of Dimenhydrinate 100 mg. Caution: to be dispensed only by or on the prescription of a physician," "Tablets Water Purification Individual (Halazone) * * * Each tablet contains P-Sulfonedichloramido Benzoic Acid (1/16 Grain) Sodium Carbonate Sodium Chloride Boric Acid," "Halazone Tablets (p-sulfonedichloramido benzoic acid 0.004 gm.; sodium borate and chloride)," or "Water Purification Tablets * * * Each Tablet Contains 0.004 Gm. (1/16 Grain) of Halazone."

RESULTS OF INVESTIGATION: Analysis showed that the *halazone tablets* contained from 19 percent to 67 percent of the labeled amount of halazone. The National Formulary requires that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 6–14–55; amended 6–15–55, W. Dist. Tenn.

CHARGE: *Halazone tablets.* 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

Dramamine tablets. 503 (b) (4)—the article, when shipped, was a drug subject to 503 (b) (1) (C), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–21–55. Consent—destruction.

4885. First aid packets and halazone tablets. (F. D. C. No. 38179. S. Nos. 18–374/5 M.)

QUANTITY: 13,775 *first aid packets* and 73 cases, 300 100-tablet btls. each, of *halazone tablets* at New York, N. Y.

SHIPPED: 10–21–52 and 3–22–55, from Louisville, Ky., and Memphis, Tenn.

RESULTS OF INVESTIGATION: An examination of 7 *first aid packets* showed that 4 contained an envelope holding 5 grams of sulfanilamide.

Analysis showed that the *halazone tablets* contained less than 90 percent of the labeled amount of halazone. The National Formulary requires that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 6–10–55, S. Dist. N. Y.

CHARGE: *Halazone tablets.* 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium; and while held for sale, its strength differed from the standard set forth in such compendium.

First aid packets. 503 (b) (4)—a component of the article, sulfanilamide, was a drug which was subject to 21 U. S. C. 503 (b) (1); and, while held for sale, its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–14–55. Default—destruction.

4886. First aid packets. (F. D. C. No. 38215. S. No. 18–378 M.)

QUANTITY: 2,668 packets at New York, N. Y.

SHIPPED: 3–27–52 and 3–31–52, from Austin, Tex., and Memphis, Tenn.

RESULTS OF INVESTIGATION: Examination showed that a substantial number of the *first aid packets* contained an envelope holding 5 grams of sulfanilamide, none of which bore the prescription legend.

LIBELED: 7–1–55, S. Dist. N. Y.

CHARGE: 503 (b) (4)—the article, while held for sale, contained a drug to which 503 (b) (1) (B) applied, and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–22–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4887. **Savatan capsules.** (F. D. C. No. 37996. S. No. 13-551 M.)

QUANTITY: 17 boxes at Philadelphia, Pa., in possession of Al Breitman, t/a Bright Cut Rate Drugs.

SHIPPED: 7-25-52, from St. Louis, Mo.

LABEL IN PART: (Box) "24 Capsules Savatan Each capsule contains Apiol (Green) 5 min. Caution: Federal law prohibits dispensing without prescription."

RESULTS OF INVESTIGATION: Bright Cut Rate Drugs was a retail establishment not regularly engaged in the dispensing of prescription drugs and did not have a licensed pharmacist in attendance.

LIBELED: 5-27-55, E. Dist. Pa.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use, and the article was not exempted from such requirement since it was a prescription drug and was in the possession of a retail establishment which was not a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs.

DISPOSITION: 7-27-55. Default—destruction.

4888. **Cephasal tablets.** (F. D. C. No. 37904. S. No. 3-236 M.)

QUANTITY: 370 btls. at Hartford, Conn.

SHIPPED: During 1952 and 1953, from Newark, N. J., by Chase Chemical Co., Inc.

LABEL IN PART: (Btl.) "100 Tablets No. 253 Cephasal * * * Anodyne and Antipyretic Distributed by Richale Pharmaceutical Co. * * * Hartford, Conn. Each tablet contains: Acetylsalicylic Acid 3.5 grains Caffeine Citrated 0.5 grains Phenacetin 2.5 grains Ascorbic Acid 25.0 mg. To be used by or on the prescription of a physician only."

RESULTS OF INVESTIGATION: Examination showed that the article contained 21.3 milligrams of ascorbic acid, 2.62 grains of aspirin (acetylsalicylic acid), 0.47 grain of salicylic acid, and 0.22 grain of caffeine, per tablet.

LIBELED: 3-25-55, Dist. Conn.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess; and 502 (a)—while held for sale, the label statement "Each tablet contains: Acetylsalicylic Acid 3.5 grains Caffeine Citrated 0.5 grains * * * Ascorbic Acid 25.0 mg." was false and misleading.

502 (a)—the statement on the label of the article, when shipped, namely, "To be used by or on the prescription of a physician only," was false and misleading since the statement represented that the article was one which should be used only under the supervision of a physician, when such was not the case; and 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use since its label failed to bear directions under which the article could safely be used by the layman and a statement of the purposes for which it was intended.

DISPOSITION: 5-18-55. Consent—destruction.

4889. Glo-Vita mineral tablets and Glo-Vita multivitamin tablets. (F. D. C. No. 38257. S. Nos. 6–895/900 M.)

QUANTITY: 116 360-tablet btls. and 82 120-tablet btls. of *Glo-Vita mineral tablets* and 30 360-tablet btls., 67 180-tablet btls., and 57 60-tablet btls. of *Glo-Vita multivitamin tablets*, at Midvale, Utah, in possession of Ellis L. Richardson.

SHIPPED: Between 5–5–55 and 7–1–55, from Los Angeles, Calif., by Glo-Vita Corp.

LABEL IN PART: (Btl.) "Glo-Vita Mineral Tablets 4 Mineral Tablets Daily Will Supply: Iron (Ferrous Gluconate) 30 Mg. MDR 300% Iodine (Kelp) 0.3 Mg. MDR 300% Manganese (Gluconate) 1 Mg. Copper (Gluconate) 0.3 Mg. Cobalt (Gluconate) 0.2 Mg. Nickel (Phosphate) 0.1 Mg. Zinc (Phosphate) 0.3 Mg. Magnesium (Trisilicate) 1 Mg. Calcium (Bone Phosphate) 427 Mg. MDR 54% Phosphorus (Bone Phosphate) 194 Mg. MDR 28% Fluorine (Bone Phosphate) 0.6 Mg. Potassium (Kelp) 21 Mg. Sulfur (Kelp) 2 Mg. Chlorine (Kelp) 25 Mg. Sodium (Kelp) 7 Mg. In a base of a sedimentary Mineral deposit (Montmorillonite) with excipients and binders. * * * Directions: Take 2 tablets with morning and noon meals as a dietary supplement or as directed by your doctor" and "Glo-Vita Multivitamin Tablets * * * 2 Tablets Daily Will Supply: Vitamin A (Vitamin A Acetate) 8,000 USP Units MDR 200% Vitamin D (Irradiated Ergosterol) 1,000 USP Units MDR 250% Vitamin B–1 (Thiamin) 6 Mg. MDR 600% Vitamin B–2 (Riboflavin) 5 Mg. MDR 250% Vitamin B–6 (Pyridoxine (HCl) 1 Mg. Vitamin B–12 (Fermentation Concentrate) 5 Mcg. Vitamin C (Ascorbic Acid) 75 Mcg. MDR 250% Vitamin E (d-Alpha Tocopherol) 2 IU Calcium Pantothenate 5 Mg. Niacinamide 30 Mg. Folic Acid 0.5 Mg. Inositol 5 Mg. Para Aminobenzoic Acid 5 Mg. Rutin 1 Mg. Biotin 2 Mcg. Vitamin K (Menadione) 1 Mg. Choline (Bitartrate) 5 Mg. Chlorophyll (Chlorophyllins) 2 Mg. Cabbage Juice Extract 65 Mg. Lemon Peel Infusion 5 Mg. In a base of concentrates of Alfalfa, Water Cress and Parsley with excipients, binders and certified color in coating. * * * Directions: Take 1 tablet with morning and noon meals as a dietary supplement, or as directed by your doctor."

ACCOMPANYING LABELING: Copies of the Glo-Vita sales manual and leaflets entitled "Why Suffer?"

RESULTS OF INVESTIGATION: The articles were promoted for sale through sales presentations given by representatives of the Glo-Vita Corp. During these sales presentations, the agents of Glo-Vita Corp. orally recommended the article for use in the treatment of various diseases.

LIBELED: On or about 8–18–55, Dist. Utah.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for chronic fatigue, neuritis, arthritis, constipation, anemia, migraine headache, vague aches and pains, skin disorders, high and low blood pressure, heart conditions, and rheumatism; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of rheumatic fever, duodenal ulcers, muscular dystrophy, arthritis, cirrhosis of the liver, psoriasis, fatigue, heart trouble, diabetes, eczema, hay fever, low blood pressure, and overweight and underweight, which were the conditions for which the article was recommended orally by the agents of Glo-Vita Corp.

DISPOSITION: 7–17–56. Default—the article was delivered to a charitable institution, and the accompanying labeling was destroyed.

4890. Rectal treatment. (F. D. C. No. 37633. S. No. 3–767 M.)

QUANTITY: 70 labeled boxes and 144 unlabeled boxes, each containing 12 *suppositories* and 1 1-oz. tube of *ointment*, at Rochester, N. Y., in possession of Pharma-Seal, Inc.

SHIPPED: 11–4–54, from Jersey City, N. J.

LABEL IN PART: (Box) "P & S Combination Rectal Treatment Relief Of The Pain And Discomfort Of Internal And External Piles And Rectal Irritations One Dozen Suppositories One Ounce Ointment * * * The active ingredients of the ointment and suppositories are: Istrian Nutgalls, Zinc Oxide, and Ethyl Aminobenzoate."

RESULTS OF INVESTIGATION: The consignee applied the above-described label to the labeled boxes of the article which originally had been shipped unlabeled.

LIBELED: 1–31–55, W. Dist. N. Y.

CHARGE: 502 (b) (1) and (2)—the article, while held for sale, failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein; 502 (f) (1)—the labeling of the article failed to bear adequate directions for use; and 502 (f) (2)—the labeling of the article failed to bear a warning against the use of the article in case of bleeding piles.

DISPOSITION: 3–4–55. Consent—claimed by Pharma-Seal, Inc., and relabeled.

4891. Hemorrhoidal suppositories and pile and rectal ointment. (F. D. C. No. 37993. S. Nos. 12–690/2 M.)

QUANTITY: 18 boxes of *hemorrhoidal suppositories* and 54 cartoned tubes of *pile and rectal ointment* at Hackensack, N. J.

SHIPPED: Between 12–20–54 and 4–25–55, from New York, N. Y., by Hanex Co.

LABEL IN PART: (Box) "One Dozen * * * Hanex Haemorrhoidal Suppositories * * * Anti-Septic Astringent * * * Components—Zinc Oxide, Balsam Peru, Menthol, Aluminum Acetate, Benzocaine, Camphor, Cocoa Butter"; (carton) "Hanex Pile and Rectal Ointment"; (tube) "Hanex * * * Ointment Contains: Menthol, Camphor, Alumine Acetate, Zinc Oxide, Benzocaine, Balsam Peru in a base of Olive Oil, Lanolin, and Petrolatum."

ACCOMPANYING LABELING: Leaflet entitled "at your druggist Hanex Pile Remedy."

LIBELED: 5–27–55, Dist. N. J.

CHARGE: 502(a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles were an adequate and effective treatment for itching and bleeding piles and irritated anus; and 502 (f) (2)—the labeling of the articles failed to bear adequate warnings against use in bleeding piles.

DISPOSITION: 6–28–55. Default—destruction.

4892. Devine's Zina-Ray oil and inhalers. (F. D. C. No. 37894. S. Nos. 8–149/51 M.)

QUANTITY: 100 1-oz. btls., 115 3-oz. btls., and 50 8-oz. btls. of *Devine's Zina-Ray oil* and 2,650 *inhalers* at Kansas City, Mo., in possession of Cleo Cissell.

SHIPPED: 12–30–54, from Chicago, Ill.

LABEL IN PART: (Btl.) "Devine's Zina-Ray Oil Aids in the Relief of Coughs and Colds, Stiff Joints and Sore Muscles Due to Overexertion or Fatigue Contains—Eucalyptus Oil, Menthol and Gum Camphor"; (inhaler) "Devine's * * * Inhaler * * * Insert a few drops of Devine's Zina-Ray Oil into the end of inhaler."

ACCOMPANYING LABELING: Circulars designated "Pain Sufferers Don't Take Dope For Muscular Aches and Pains Due To Over Exertion and Fatigue Use Devine's Zina-Ray Oil."

RESULTS OF INVESTIGATION: The *Devine's Zina-Ray oil* consisted of a yellow oil having the odor of eucalyptus, camphor, and menthol. The *inhaler* consisted of glass tubing approximately 70 millimeters long and 12 millimeters in diameter. One end was constricted to an opening of 5 millimeters in diameter, and the other end was closed with a piece of cork containing a small hole. The tube contained a small piece of unmedicated cotton.

LIBELED: On or about 3–18–55, W. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of the *Devine's Zina-Ray oil* and the *inhalers*, while held for sale, failed to bear adequate directions for use in the relief, prevention, and treatment of the conditions for which such articles were intended, namely, in the treatment and prevention of sinusitis and colds, in the treatment of bronchitis, hay fever, arthritis, stiff joints, bursitis, earache, and neuralgia, in the prevention of flu and pneumonia, and for the relief of all aches and pains of the body, which were the conditions for which the articles were intended and for which they were offered orally at Kansas City, Mo., by Cleo Cissell, a representative of the shipper, Devine's Remedies, Inc., Chicago, Ill.

DISPOSITION: 4–29–55. Default—destruction.

4893. Atomotrone device (2 seizure actions). (F. D. C. Nos. 37979, 37980. S. Nos. 9–393 M, 9–398 M, 14–914/5 M, 14–960 M, 14–964 M., 15–448/53 M, 15–458 M, 15–561/8 M, 15–576/8 M.)

QUANTITY: 40 *Atomotrone devices* at Hawthorne and elsewhere within the Southern District of California; and, in addition, 40 *Atomotrone devices* at Salinas and elsewhere within the Northern District of California.

SHIPPED: Between 12–1–54 and 5–23–55, from Dallas and McKinney, Tex.

ACCOMPANYING LABELING: Pamphlets entitled "The Atomotrone" and "Testimonials by Users of The Atomotrone," pads of forms entitled "Sale Agreement," and individual testimonial letters.

RESULTS OF INVESTIGATION: The *Atomotrone device* consisted of a metal cabinet containing an electrically operated sunlamp positioned in such a manner that light emanating from the lamp would fall on jugs of water placed in the cabinet. Several sheets of colored glass were interposed between the lamp and the jugs. The device contained also a one-tube radio wave generator.

In operation, jugs of tap water were placed in the device and subjected to the "action" of the rays from the sunlamp and the radio waves generated by the one-tube transmitter. According to the accompanying labeling, ingestion of water treated in the device was effective in the treatment of a number of disease conditions.

LIBELED: 5–24–55, S. Dist. Calif. and N. Dist. Calif.

CHARGE: 502 (a)—the labeling of the *Atomotrone devices*, when shipped and while held for sale, when taken as a whole, as well as through specific claims, and in the setting in which it was presented, contained false and misleading representations and suggestions that the devices provided an adequate and effective treatment for the following conditions: Acidosis, anemia, apoplexy stroke, arthritis, bad health, baldness, blindness, Bright's disease, including chronic Bright's disease, congenital Bright's disease, and incurable Bright's disease, cancer, cardiac paralysis, cataracts, chronic disease, chronic indigestion, colonic cancer, colon spasm, deafness, diabetes, dropsy, eczema, enlarged heart, excessive menstrual bleeding, fibroid tumor of uterus, frequent colds, gallstones, gas, glandular deficiency, goiter, growths in stomach and rectum, hacking cough, heart attack, heart disease (all types), heart trouble, heart valve disease, hemorrhages, hemorrhoids, high blood pressure, high fevers, hypertension, indigestion, kidney disease, kidney stones, leg pains, low blood pressure, menstrual cramps, nausea, nephritis, nervous exhaustion, nervousness, numbness, pains in abdomen, arms, back, chest, heart, hips, liver, neck, shoulders, and stomach, palpitatiton of heart, paralysis, paralysis agitans, penicillin poisoning, pernicious anemia, postoperative lack of energy and vitality, pressure around heart, prostatitis, pus in the kidneys, pus in the lungs, rapid heart, rectal diseases, severe headaches, shortness of breath, sinus disease, sore throat, stomach hemorrhages, stomach trouble, stomach ulcerations, suspected tuberculosis, toxic goiter with ophthalmic symptoms, tuberculosis, tumors, ulcers, virus infection, and weakness in legs and hands.

The labeling of the devices, when taken as a whole, as well as through specific claims, and in the setting in which it was presented, contained also statements which created the following false and misleading impressions: (a) that competent medical treatment of serious diseases, such as diabetes, cancer, heart trouble, tuberculosis, and many others, might be safely discontinued by persons who drank water and ate food treated in the devices; (b) that the shortwave unit of the devices produced an ultra high frequency wave; (c) that the shortwave unit of the devices produced radiation which broke up water molecules in jars of water placed in the devices; (d) that there were no chemical cures for any ailment known to man; (e) that food which was treated in the devices was detoxified and mineralized; and (f) that ordinary tap water which was treated in the devices became a source of substantial amounts of vitamins and minerals.

The labeling of the devices also was false and misleading since it represented and suggested that the devices were invented by William Estep and purported to set forth high lights in William Estep's life portraying him as licensed to practice medicine in the State of Florida and as a renowned scientist and benefactor of mankind, but the labeling failed to reveal the following facts, which were material in the light of such representations, suggestions, and portrayal: (a) that William Estep had been prohibited from practicing medicine in Florida; (b) that William Estep had been convicted and sentenced in Illinois to imprisonment for 3 to 5 years and to pay a fine of $2,000 for conspiracy to violate the Medical Practice Act, for conspiracy to perpetrate a confidence game, and for conspiracy to obtain money under false pretenses, arising out of his treatment of patients with "atomic water" and various other therapeutic and diagnostic measures, which had been described by the Appellate Court of Illinois as an activity "to deceive and defraud the unfor-

tunate and unwary"; and (c) that William Estep was a fugitive from justice in the State of Illinois.

502 (f) (1)—the labeling of the devices, when shipped and while held for sale, failed to bear adequate directions for use; and 501 (c)—the strength of the devices differed from, and their quality fell below, that which they purported and were represented to possess.

DISPOSITION: 7–28–55 and 11–16–55. Default—delivered to the Food and Drug Administration.

4894. Atomotrone device. (Inj. No. 291.)

COMPLAINT FOR INJUNCTION FILED: 6–14–55, N. Dist. Calif., against Claude O. Martin, Modesto, Calif., who was the holder of a franchise obtained from F. C. Cretcher, McKinney, Tex., for the exclusive distribution in California of a device known as *Atomotrone*.

NATURE OF DEVICE: The device included a kitchen cabinet, sunlamp, shortwave unit, connecting wires, colored glass filters, and 4 1-gallon jars. It purported to be capable of "irradiating" and imparting therapeutic properties to ordinary water and food.

The complaint alleged that the device was incapable of imparting therapeutic properties to water or food, and could not be helpful in any other manner in the treatment or prevention of disease.

NATURE OF BUSINESS: The complaint alleged that the defendant purchased *Atomotrone devices* from F. C. Cretcher and others in Texas; that the devices were transported from Texas, consigned to the defendant at Modesto, Calif.; that the defendant, through his own efforts and through agents, promoted the sale of the devices throughout the State of California; that each purchaser of the device was offered a commission by the defendant for each sale which the purchaser was instrumental in bringing about, thus, in effect, making each purchaser an agent; and that the devices, when introduced into interstate commerce and while held for sale after shipment in interstate commerce, were accompanied by the labeling described below which constituted a part of the distributional scheme to promote the sale of the devices.

ACCOMPANYING LABELING: Pamphlets entitled "The Atomotrone" and "Testimonials by Users of The Atomotrone," pads of forms entitled "Sale Agreement," and individual testimonial letters.

CHARGE: The complaint charged that when the defendant caused the devices to be introduced into interstate commerce and when he received the devices in interstate commerce, the devices were misbranded and adulterated as follows:

502 (a), the labeling of the devices, when taken as a whole as well as through specific claims, and in the setting in which it was presented, contained the following false and misleading representations:

(a) That the devices would provide an adequate and effective treatment for the following conditions: Acidosis, anemia, apoplexy stroke, arthritis, bad health, baldness, blindness, Bright's disease, including chronic Bright's disease, congenital Bright's disease, and incurable Bright's disease, cancer, cardiac paralysis, cataracts, chronic disease, chronic indigestion, colonic cancer, colon spasm, deafness, diabetes, dropsy, eczema, enlarged heart, excessive menstrual bleeding, fibroid tumor of uterus, frequent colds, gallstones, gas, glandular deficiency, goiter, growths in stomach and rectum, hacking cough, heart attack, heart disease (all types), heart trouble, heart valve disease,

hemorrhages, hemorrhoids, high blood pressure, high fevers, hypertension, indigestion, kidney disease, kidney stones, leg pains, low blood pressure, menstrual cramps, nausea, nephritis, nervous exhaustion, nervousness, numbness, pains in abdomen, arms, back, chest, heart, hips, liver, neck, shoulders, and stomach, palpitation of heart, paralysis, paralysis agitans, penicillin poisoning, pernicious anemia, postoperative lack of energy and vitality, pressure around heart, prostatitis, pus in the kidneys, pus in the lungs, rapid heart, rectal diseases, severe headaches, shortness of breath, sinus disease, sore throat, stomach hemorrhages, stomach trouble, stomach ulcerations, suspected tuberculosis, toxic goiter with ophthalmic symptoms, tuberculosis, tumors, ulcers, virus infection, and weakness in legs and hands;

(b) That competent medical treatment of serious diseases, such as diabetes, cancer, heart trouble, tuberculosis, and many others, might be safely discontinued by persons who drank water and ate food treated in the devices;

(c) That the shortwave unit of the devices produced an ultra high frequency wave;

(d) That the shortwave unit of the devices produced radiation which broke up water molecules in jars of water placed in the devices;

(e) That there were no chemical cures for any ailment known to man;

(f) That food which was treated in the devices was detoxified and mineralized; and

(g) That ordinary tap water which was treated in the devices became a source of substantial amounts of vitamins and minerals.

502 (a), the labeling of the devices also was false and misleading since it represented and suggested that the devices were invented by William Estep and purported to set forth high lights in William Estep's life, portraying him as licensed to practice medicine in the State of Florida and as a renowned scientist and benefactor of mankind, but the labeling failed to reveal the following facts, which were material in the light of such representations, suggestions, and portrayal:

(a) That William Estep had been prohibited from practicing medicine in Florida [see *Estep* v. *State*, 23 So. (2d) 482 (Sup. Ct. Fla., 1945)];

(b) That William Estep had been convicted and sentenced in Illinois to imprisonment for 3 to 5 years and to pay a fine of $2,000 for conspiracy to violate the Medical Practice Act, for conspiracy to perpetuate a confidence game, and for conspiracy to obtain money under false pretenses, arising out of his treatment of patients with "atomic water" and various other therapeutic and diagnostic measures which have been described by the Appellate Court of Illinois as an activity "to deceive and defraud the unfortuniate and unwary" [see *People* v. *Estep*, 346 App. 132, 138 (Appellate Court, First District, February 11, 1952)]; and

(c) That William Estep was a fugitive from justice in the State of Illinois [see *People* v. *Estep*, 413 Ill. 437 (Sup. Ct. Ill., November 20, 1952), cert. den. 345 U. S. 970; *Ex parte William Estep*, 276 S. W. (2d) 284 (Texas Ct. of Crim. App., January 5, 1955)].

502 (f) (1), the labeling of the devices failed to bear adequate directions for use; and

501 (c), the strength of the devices differed from, and their quality fell below, that which they purported and were represented to possess.

The complaint alleged also that the defendant caused the devices to become misbranded within the meaning of 502 (a) while held for sale after shipment

in interstate commerce by incorporating into the labeling of the devices testimonial letters which made additional false and misleading therapeutic claims.

DISPOSITION: 6–21–55. The defendant having consented, the court entered a decree of permanent injunction enjoining the defendant from doing any of the following acts with respect to the *Atomotrone devices* or with respect to any similar device or any component, part, or accessory thereof:

1. Causing to be introduced or delivered for introduction into interstate commerce any such article which was misbranded or adulterated as alleged in the complaint;

2. Receiving in interstate commerce and delivering for pay or otherwise any such misbranded or adulterated article; and

3. Causing the association of labeling with any such article, or by making claims for such article, in any other manner while the article was held for sale after shipment in interstate commerce which would result in the article being misbranded or adulterated in any of the alleged respects.

4895. Uranium ore. (F. D. C. No. 37901. S. No. 10–716 M.)

QUANTITY: 8 plastic leather pads, some containing 4 to 5 lbs. and some containing 15 to 20 lbs., of *uranium ore;* a number of hot water btls., each containing 3 lbs., of *uranium ore;* and 175 lbs. of loose *uranium ore* at Sauk City, Wis.

SHIPPED: During August and September 1954, from Edgemont, S. Dak.

RESULTS OF INVESTIGATION: The *uranium ore* was shipped in bulk and, after receipt, it was repacked by Royal A. Dickson, doing business as Gama-Ray Co., Sauk City, Wis.

The ore was represented by Royal A. Dickson, in the course of sales talks given by him at Sauk City, as effective in the treatment of the disease conditions described below. Examination showed that the ore emitted a very small amount of radioactivity.

LIBELED: 3–29–55, W. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in the treatment of the diseases and conditions for which it was intended, namely, arthritis, bursitis, and blindness.

DISPOSITION: 5–7–55. Default—delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4896. Chamomile flowers. (F. D. C. No. 38285. S. No. 29–415 M.)

QUANTITY: 19 110-lb. bales at New York, N. Y.

SHIPPED: 9–15–54, from Hungary.

LIBELED: 8–22–55, S. Dist. N. Y.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 9–12–55. Default—destruction.

4897. Cut dog grass. (F. D. C. No. 38242. S. No. 29–401 M.)

QUANTITY: 2,600 lbs. in 26 bags at New York, N. Y.

SHIPPED: 12–10–52, from Chehalis, Wash.

LIBELED: 7–26–55, S. Dist. N. Y.

CHARGE: 501 (a) (1)—contained insects while held for sale.

DISPOSITION: 8–22–55. Default—destruction.

4898. Passionflower herb. (F. D. C. No. 38400. S. Nos. 31–945/6 M.)

QUANTITY: 7 290-lb. bales at Philadelphia, Pa.

SHIPPED: 5–16–55 and 6–22–55, from Boone, N. C., by Wilcox Drug Co.

LIBELED: 8–19–55, E. Dist. Pa.

CHARGE: 501 (a) (1)—contained rodent hairs, insects, and insect parts; and 501 (a) (2)—prepared and packed under insanitary conditions.

DISPOSITION: 10–20–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS *

4899. Phenobarbital sodium (powder). (F. D. C. No. 38234. S. No. 21–661 M.)

QUANTITY: 39 cartons, 25 5-cc. ampuls each, at Wilmington, Del.

SHIPPED: 4–15–55, from Philadelphia, Pa., by DuMont Pharmacal Co.

LABEL IN PART: (Carton) "25 Ampules Phenobarbital, Sodium Powder For Injection 2 Gr. per cc. Sterile Dissolve contents of ampule in 1 cc. to 3 cc. of sterile distilled water"; (ampul) "5 cc. Ampoule Sodium Phenobarbital Contains: 2 Grains Dry Powder Sterile–Intramuscular."

RESULTS OF INVESTIGATION: Analysis of the individual containers showed that they contained 23 percent more than the declared amount of phenobarbital sodium (powder).

LIBELED: On or about 7–14–55, Dist. Del.

CHARGE: 501 (b)—the article, when shipped, purported to be and was represented as "Phenobarbital Sodium Powder," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium since the article deviated from the declared weight by more than 7.5 percent, the maximum deviation permitted by the standard; and 502 (a)—the label statement "2 Gr. per cc." was false and misleading.

DISPOSITION: 8–11–55. Default—relabeled and delivered to a charitable institution.

4900. Dietabs (2 seizures). (F. D. C. Nos. 36422, 37060. S. Nos. 60–514/6 L, 60–671/3 L.)

QUANTITY: 80 1,000-tablet btls. and 2,015 100-tablet btls. at Miami, Fla.

SHIPPED: 11–11–53 and 3–23–54, from Brooklyn, N. Y., by Bonded Laboratories.

LABEL IN PART: (Btl.) "Dietabs Series B No. 1 [or "2" or "3"] (T. M.) Sugar Coated Each Tablet contains: Amphetamine Sulphate 1/12 gr. * * * Caution: Federal law prohibits dispensing without a prescription."

LIBELED: 3–1–54 and 8–20–54, S. Dist. Fla.

CHARGE: 501 (c)—the strength of the tablets, when shipped, differed from that which they purported and were represented to possess, namely, 1/12 grain of amphetamine sulfate per tablet; and 502 (a), the label statement "Each Tablet contains: Amphetamine Sulphate 1/12 gr." was false and misleading as applied to the tablets, which contained less than 1/12 grain of amphetamine sulfate per tablet.

DISPOSITION: 5–7–54 and 9–23–54. Default—destruction.

*See also Nos. 4882, 4884, 4885, 4888, 4893, 4894.

4901. Super Potency liver, iron, B complex with folic acid capsules. (F. D. C. No. 38230. S. No. 19–987 M.)

QUANTITY: 15 100-capsule btls. in interstate commerce at Washington, D. C.

LABEL IN PART: (Btl.) "Super Potency Liver, Iron, B Complex With Folic Acid * * * Recommended for the prevention of Vitamin B deficiency and the relief of secondary or nutritional anemia."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of vitamin B_1.

LIBELED: 7–8–55, Dist. Columbia.

CHARGE: 501(c)—the strength of the article, while in interstate commerce, differed from that which it purported and was represented to possess, namely, 1,665 U. S. P. units of vitamin B_1, per capsule; and 502(a)—the label statement "Each capsule contains the equivalent of * * * Vitamin B_1 (Thiamine Hydrochloride 5 mg.) 1665 U. S. P. Units" was false and misleading. The libel alleged also that three other products, namely *Rybutol Gelucaps*, *Good Diet vitamin capsules*, and *Good Diet vitamin mineral capsules*, were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 8–10–55. Default—destruction.

4902. Elixir Betwelv. (F. D. C. No. 37928. S. No. 3–242 M.)

QUANTITY: 81 btls. at Hartford, Conn.

SHIPPED: During November 1952, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 60 percent of the declared amount of vitamin B_{12}.

LIBELED: 4–12–55, Dist. Conn.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 5 micrograms of vitamin B_{12} per 5 cc.; and, 502 (a)—the label statement "Each 5 cc. (approx. 1 teaspoonful) Contains: Vitamin B_{12} * * * 5 mcg." was false and misleading.

DISPOSITION: 7–25–55. Default—destruction.

4903. Saccharin sodium. (F. D. C. No. 38227. S. No. 11–899 M.)

QUANTITY: 15 cases, 50 1-lb. cans each, at New York, N. Y.

SHIPPED: The article was shipped to Tangier, Morocco, and returned on 3–30–48.

RESULTS OF INVESTIGATION: Analysis showed that the article contained not more than 88.8 percent anhydrous saccharin sodium.

LIBELED: 7–26–55, S. Dist. N. Y.

CHARGE: 501 (b)—the article, while held for sale, purported to be and was represented as "Saccharin Sodium," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in such compendium in that it contained less than 98 percent anhydrous saccharin, the minimum permitted by the standard, and, further, in that it failed to meet the tests specified in the standard for color, readily carbonizable substances, and alkalinity.

DISPOSITION: 8–18–55. Default—destruction.

4904. Halazone tablets. (F. D. C. No. 38177. S. No. 18–373 M.)

QUANTITY: 109 cases, 300 100-tablet btls. each, at New York, N. Y.

SHIPPED: Prior to 4–1–52, from Memphis, Tenn.

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 0.5 percent to 96.3 percent of the declared amount of halazone. The National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 6–9–55, S. Dist. N. Y.

CHARGE: 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 7–7–55. Default—destruction.

4905. Halazone tablets. (F. D. C. No. 38182. S. No. 18–377 M.)

QUANTITY: 99 cases, 300 100-tablet btls. each, at New York, N. Y.

SHIPPED: 4–1–52, from Memphis, Tenn.

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 0.68 percent to 109 percent of the labeled amount of halazone. The National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 6–14–55, S. Dist. N. Y.

CHARGE: 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 7–12–55. Default—destruction.

4906. Halazone tablets. (F. D. C. No. 38186. S. No. 18–379 M.)

QUANTITY: 84 cases, 300 100-tablet btls. each, at New York, N. Y.

SHIPPED: Sometime during June or July 1954, from Memphis, Tenn.

RESULTS OF INVESTIGATION: Analysis showed that the article contained from 1.4 percent to 90.3 percent of the labeled amount of halazone. The National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 6–20–55, S. Dist. N. Y.

CHARGE: 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 7–12–55. Default—destruction.

4907. Halazone tablets. (F. D. C. No. 38246. S. Nos. 9–721/2 M.)

QUANTITY: 31 cases, 300 100-tablet btls. each, and 200 100-tablet btls., at Los Angeles, Calif.

SHIPPED: During 1950 and 1951, from outside the State of California.

LABEL IN PART: (Btl.) "Water Purification for Treating Water in Canteens * * * Halazone Tablets (P-sulfonedichloramidobenzoic acid 0.004 Gm; sodium borate and chloride)."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 9.8 percent to 112.3 percent of the labeled amount of halazone. The National Formulary provides that halazone tablets contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 7–22–55, S. Dist. Calif.

CHARGE: 501 (b)—the article, while held for sale, purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 8–15–55. Default—destruction.

4908. Petronet dressings. (F. D. C. No. 38218. S. No. 29–364 M.)

QUANTITY: 123 tins at Hackensack, N. J.

SHIPPED: 4–4–55, from Leicester, England, by Dalmas, Ltd.

LABEL IN PART: (Tin) "Petronet Dressings A non-adhesive open mesh petroleum gauze dressing * * * Sterilized * * * Size 8 yards x 3¾ inches * * * Made in England."

RESULTS OF INVESTIGATION: Examination showed that the article was not sterile but was contaminated with living micro-organisms.

LIBELED: 6–30–55, Dist. N. J.

CHARGE: 501 (c)—the purity and quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the label statement "Sterilized" was false and misleading.

DISPOSITION: 8–12–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4909. Paracyl tablets. (F. D. C. No. 37613. S. Nos. 3–816/7 M.)

QUANTITY: 1 drum containing 19,900 tablets, and 94 btls., 50-tablets each, at Rochester, N. Y., in possession of Pharma-Seal, Inc.

SHIPPED: 11–22–54, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: The tablets were shipped in interstate commerce in bulk, and, upon receipt by the consignee, a number of the tablets were repacked into bottles.

LIBELED: 1–19–55, W. Dist. N. Y.

CHARGE: 502 (a)—the labeling of the article (as repackaged), while held for sale, contained false and misleading representations that it was an adequate and effective treatment for arthritis and rheumatism.

DISPOSITION: 3–4–55. Consent—claimed by Pharma-Seal, Inc. The article was relabeled.

4910. Rhu-Mart tablets. (F. D. C. No. 37684. S. No. 11–830 M.)

QUANTITY: 1,920 cartoned btls., each containing 60 tablets, at Newark, N. J., in possession of Rhu-Mart Drug Co.

SHIPPED: 12–1–54, from Cleveland, Ohio.

*See also Nos. 4882, 4888, 4889, 4891, 4893, 4894, 4899, 4901, 4902, 4908.

LABEL IN PART: (Carton & btl.) "Rhu-Mart Tablets For Relief of Pains of Arthritis Rheumatism Neuritis Sciatica Lumbago Bursitis Active Ingredients Para-Aminobenzoic Acid (3 grs.) 0.2 GM. Sodium Salicylate (5 grs.) 0.3 GM. Ascorbic Acid 50. mgm. Rhu-Mart Drug Co. Newark, New Jersey."

ACCOMPANYING LABELING: A window streamer entitled "Rhu-Mart Tablets for Arthritis Rheumatism" and leaflets entitled "Rhu-Mart Tablets Rheumatism? Arthritis? Neuritis? Sciatica? Lumbago? Bursitis?"

RESULTS OF INVESTIGATION: The article was shipped in bulk from Cleveland, Ohio, and, after its receipt by the consignee, was repacked into the above-described cartons and bottles. The leaflets and window streamer were printed locally for the consignee.

LIBELED: 3–1–55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for rheumatism, arthritis, neuritis, sciatica, lumbago, and bursitis.

DISPOSITION: 5–24–55. Consent—claimed by Rhu-Mart Drug Co. and relabeled.

4911. Magonate tablets and Antabex tablets. (F. D. C. No. 37647. S. Nos. 3–778/9 M.)

QUANTITY: 1 drum containing 22,900 *Magonate tablets* and 1 btl. containing 5.000 *Antabex tablets* at Auburn, N. Y., in possession of Bexatol Vitamin Products, Inc.

SHIPPED: 3–23–54, from Camden, N. J., by Olmstead Laboratories, Inc.

LABEL IN PART: (Drum) "Magonate Each tablet contains Calcium Carbonate precip. 3.5 gr. Magnesium Carbonate 2.5 gr. Bismuth Subcarbonate 1.0 gr. Aromatics q. s. Dose: 2 or 3 tablets 3 or 4 times daily. * * *Olmstead Laboratories Camden New Jersey"; (btl.) "Antabex Tablets * * * Each tablet contains: Calcium Carbonate Precip. 3.5 gr. Magnesium Carbonate 2.5 gr. Bismuth Subcarbonate 1.0 gr. Aromatics q. s. Dose: 2 or 3 tablets 3 or 4 times daily. * * * Distributors Bexatol Vitamin Products, Inc. Auburn, New York."

RESULTS OF INVESTIGATION: The tablets were shipped from Camden, N. J., in bulk, and, after their receipt by the consignee, a number of the tablets were repackaged into the above-described bottle.

LIBELED: 2–11–55, N. Dist. N. Y.

CHARGE: 502 (a)—the labeling of the tablets, when shipped and while held for sale, contained false and misleading representations that the article was effective for the treatment of peptic ulcers.

DISPOSITION: 3–22–55. Default—delivered to a charitable institution for use as an antacid preparation.

4912. Special Formula tablets. (F. D. C. No. 37970. S. No. 18–594 M.)

QUANTITY: 23,000 tablets in 1 drum at Newburgh, N. Y.

SHIPPED: 9–5–44, from Cedar Rapids, Iowa.

LABEL IN PART: (Drum) "Special Formula Tablets S. C. Red Each tablet contains as active ingredients: Uritone—½ Gr. Methylene Blue—⅛ Gr. Ext. Uva Ursi—½ Gr. Ext. Triticum—¼ Gr. Oil Juniper—Q. S. * * * Bulk Shipment For Repacking. To Be Properly Labeled By Consignee."

RESULTS OF INVESTIGATION: The tablets in the drum were to be repacked into bottles labeled in part "50 5 Grain S. C. Pills Solvax * * * A urinary antiseptic and diuretic used in the treatment of inflammation of the Kidneys (pyelitis), Inflammation of the Bladder (cystitis), slow and painful discharge of urine (strangury irritation of Bladder), and other inflammatory conditions of the Urinary Tract. Active Ingredients: Methenamine, Methylthionine Chloride, Extract of Uva Ursi, Extract of Triticum and Oil of Juniper. Directions Two to four pills four times daily, after meals and at bedtime, as directed by physician."

CHARGE: 502 (a)—the labeling of the article, while held for sale, namely, the bottle label, contained false and misleading representations that the article was a urinary antiseptic and diuretic which would serve as an adequate and effective treatment for inflammation of the kidneys and bladder, slow and painful discharge of urine, and other inflammatory conditions of the urinary tract.

DISPOSITION: 6–7–55. Default—destruction.

4913. 30 Plus tablets and H–100 tablets. (F. D. C. No. 37964. S. Nos. 19–225/6 M.)

QUANTITY: 131 btls. of *30 Plus tablets* and 89 btls. of *H–100 tablets* at Akron, Ohio.

SHIPPED: 1–27–55 and 2–10–55, from Los Angeles, Calif., by Pacific Mineral Industries.

LABEL IN PART: (Btl.) "30 Plus An Organic Formula Iron, Iodine and Copper in A Special Base of Mexican Damiana Leaves Honduras Sarsaparilla Root True Cramp Bark Squaw Vine Black Haw Bark of Root * * * 120 Tablets . . . A Full Month's Supply" and "H–100 Vitamins Thiamin – Riboflavin – Niacin In A Base Of Alpha Tocophrol (Vit. E) Kolo Nuts – Heart's Ease Herb Blue Cohosh Root – Capsicum * * * 100 Tablets."

ACCOMPANYING LABELING: Leaflets entitled "Organic Herbs And Minerals Containing Natural Hormones * * * 30 Plus" and "A New Formula Proven as an aid to Strengthen Heart Muscle Normalize Low Blood Pressure H – 100."

LIBELED: 5–5–55, N. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped contained false and misleading representations that the *H–100 tablets* were effective for strengthening the heart muscle and overcoming and normalizing low blood pressure and that the *30 Plus tablets* supplied significant quantities of testosterone, progesterone, and cortisone; were effective for stimulating sluggish adrenal glands and overcoming hormone depletion; would activate and nourish the glands; were effective in the treatment of "hot flashes," dizziness, nervousness, and other symptoms of the menopause; would restore normal body function; and were effective for restoring the feeling of youth in all persons over 30 years of age.

DISPOSITION: 6–7–55. Default—destruction.

4914. Kirby's M-I-M. (F. D. C. No. 37949. S. No. 19–228 M.)

QUANTITY: 54 btls. at Cleveland, Ohio, in possession of Rev. C. R. Worthy.

SHIPPED: 3–2–55, from Union, S. C.

LABEL IN PART: (Btl.) "Kirby's M–I–M * * * Contents 6 Fluid Ounces Active Ingredient Iron (Ferric) Sulfate Iron Tonic and Astringent."

ACCOMPANYING LABELING: Card entitled "Colored Man's Discovery."

RESULTS OF INVESTIGATION: The above-mentioned card was in the posssession of the consignee and was employed by him to promote sales of the article.

LIBELED: 4–22–55, N. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for pellagra, high blood pressure, stomach trouble, bleeding gums, piles, kidney and bladder troubles, cold sores, cuts, burns, scalds, nosebleed, diabetes, pyorrhea, female weakness, periodical pains, hay fever, tonsillitis, bed-wetting, sore throat, indigestion, athlete's foot, arthritis, rheumatism, ringworms, blood poison, erysipelas, sour stomach, venereal diseases, earache, swollen joints, boils, lung troubles, blood purifier, colic, dysentery, fits, insect stings, halitosis, itch, nervousness, hacking cough, abscess, change of life, and "numbers of other diseases common to the human body."

DISPOSITION: 5–27–55. Default—destruction.

4915. **Medicinal tea.** (F. D. C. No. 37971. S. No. 15–288 M.)

QUANTITY: 11 boxes at Honolulu, Hawaii.

SHIPPED: 11–26–54, from Kumamoto, Japan, by Hakusan Pharm. Co., Ltd.

LABEL IN PART: (Box) "Medicinal Tea * * * Hakusan Pharm. Co., Ltd. * * * Contents Fructus Citri Trifoliatae E. P. J. Hoelen Thea Sinensis L. E. P. J. Semen Cassiae Torae J. P. Cinnamomum Cassia Taxus Cuspidata E. P. J. Pericarpium Aurantii Nobilis E. P. J. Rhizoma Cnidii Offcinalis J. P. Rheum J. P. Ginseng One Pack (One days quantity)—19.5 g. J. P. . . . The Japanese Pharmacopeia E. P. J. . . . Extra-Pharmacopeia Japonica * * * Made in Japan."

ACCOMPANYING LABELING: Circular designated "The Correct Way To Cure Diabetes."

LIBELED: 5–13–55, Dist. Hawaii.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for diabetes, insomnia, neuralgia, polycarbuncle, polyanthrax, kidney trouble, high blood pressure, and arterial sclerosis.

DISPOSITION: 6–17–55. Default—destruction.

4916. **Wildunger herb tea.** (F. D. C. No. 37564. S. Nos. 5–511/2 M.)

QUANTITY: 2 100-lb. drums at Detroit, Mich., in possession of Botanical Mail Order House.

SHIPPED: 6–15–54 and 10–22–54, from Jersey City, N. J.

LABEL IN PART: (Drum) "Special Cut and Sifted Herb Tea Formula #141."

ACCOMPANYING LABELING: Form letters headed "Dear Friend: Knowing that you are interested," "Dear Sir or Madam: Your name was recently given to us," and "Dear Doctor: Please accept with our compliments"; circulars headed "This is It" and "Write to: Botanical Mail Order House"; and a folder headed "Wildunger Brand Herb Tea."

RESULTS OF INVESTIGATION: As received from the shipper, the article in the drums was labeled as described above. The article was to be repacked into 4- and 8-ounce cartons and ½-ounce envelopes labeled, in part, "Wildunger

Brand Herb Tea A carminative-diuretic * * * Prepared for and Distributed by Botanical Mail Order House Detroit 19, Michigan."

The accompanying labeling was prepared locally by the consignee and was used by him in direct mail advertising to customers and prospective customers, or was enclosed with samples distributed, or in packages mailed, to customers.

It was assumed that the article was of the composition declared on the labels used on the repackaged article, namely, "Active Ingredients: Anise, Peppermint, Ginger, Corn Silk, Uva Ursi, Horsetail Herb and Bucu. Also contains: Licorice, Birch Leaves and Bean Shells."

LIBELED: 1–3–55, E. Dist. Mich.; amended 1–25–55.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for metabolic disorders, gout, and diabetes.

DISPOSITION: 3–29–55. Default—destruction.

4917. Persulan. (F. D. C. No. 37640. S. No. 4–769 M.)

QUANTITY: 6 1-lb. jars, 4 8-oz. jars, 15 4-oz. jars, 19 2-oz. jars, and 9 units, each unit consisting of 5 ½-oz. jars and 1 2-oz. jar, at South Bend, Ind.

SHIPPED: Between 4–12–54 and 10–22–54, from Detroit, Mich., by Drake Laboratories, Inc.

LABEL IN PART: (Jar) "Persulan * * * Contains Balsam Peru, Precipitated Sulphur Lanolin, Resorcinol."

ACCOMPANYING LABELING: Pamphlet entitled "Persulan Hair Conditioning from the Scalp Up."

LIBELED: 2–3–55, N. Dist. Ind.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for otomycosis, barber's itch, leg itch, irritation on the hands, crusty itching scalp, skin irritation, baldness, ringworm of the scalp, scalp infections, infected scalp, scabby scalp, open sores, skin disorders, and itchy hands.

DISPOSITION: 4–27–55. Default—destruction.

4918. Uranium ore. (F. D. C. No. 37336. S. No. 85–536 L.)

QUANTITY: A quantity of *uranium ore* contained in unlabeled cloth pads on the floor, on the walls and ceiling, and on two full length benches of a 27′ x 9′ room known as the tunnel, and in 13 loose, unlabeled pads measuring approximately 13″ x 14,″ at Santa Rosa, N. Mex., in possession of H. C. Darsey, t/a Uranium Center.

SHIPPED: 7–1–54, from Picacho, Ariz.

ACCOMPANYING LABELING: A tear sheet entitled "Arthritics Seek Cure in Radioactive Mines" taken from the July 7, 1952, issue of Life magazine and a tear sheet entitled "Uranium Cure Group Moves" taken from the July 29, 1953, issue of the Tucson Daily Citizen.

RESULTS OF INVESTIGATION: A patient either would sit or recline on the uranium padded bench while undergoing the "treatment" provided by the purported radioactivity of the ore. The loose pads were provided the patient for placing over afflicted portions of the body while he was being "treated" in the tunnel.

LIBELED: 11–16–54, Dist. N. Mex.

CHARGE: 502 (a)—the accompanying labeling of the article, while held for sale, contained false and misleading representations that the article provided an effective treatment for arthritis, bursitis, sinus trouble, asthma, and "other chronic diseases."

DISPOSITION: 12–28–54. Default—destruction.

4919. Pliofilm pads. (F. D. C. No. 37687. S. No. 16–148 M.)

QUANTITY: 51 pads at Portland, Oreg.

SHIPPED: 1–11–55, from Minot, N. Dak., by J. W. Desmond.

ACCOMPANYING LABELING: A leaflet inserted in each Pliofilm pad reading "The following elements are present: Lanthanum, Praseodymium, Thorium, Cerium, Neodymium, Samarium, Dyprosium, Holmium, Erbium, Thulium, Yetterbrium Uttrium, Silicate. Activ-Ray Poultice Company 1200 S. W. Morrison Street Portland 5, Oregon;" and form letters printed on pink, yellow, blue, and white paper entitled "New Relief From Arthritis: Activ-Ray Mineral Pads."

LIBELED: 3–17–55, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, rheumatism, sinus, neuralgia, and related chronic conditions, nagging, nerve-wracking pain, for restoring health and general well-being, and for pains in back or torso pains, pains in extremities (leg, foot, hand, and arm), and in head or neck area.

DISPOSITION: 5–17–55. Default—destruction.

DRUGS FOR VETERINARY USE

4920. Aquolex and Aquodine Concentrate. (F. D. C. No. 37105. S. Nos. 75–281/2 L.)

QUANTITY: 80 100-lb. bags of *Aquolex*, and 70 cases, 6 5-lb. jars each, of *Aquodine Concentrate* at Girdletree, Md.

SHIPPED: 2–16–54 and 5–5–54, from Tampa, Fla., by F. W. Albright Laboratories.

LABEL IN PART: (Bag) "All Bright AQUOLEX Aquodine Powder Contains Calcium Phosphate, Iron Oxide, Copper Sulphate, Manganese Sulphate, Iron Sulphate, Zinc Sulphate, Aniline Dye, Anise. Combined Minerals and Salines To Mix with the Feed. For Poultry of all Ages"; (jar) "AQUODINE CONCENTRATE For Making Aquodine"; (label folded inside jar top) "Aquodine For Poultry of All Ages Contains Copper Sulphate, Iron Sulphate, Zinc Sulphate, Aniline Dye."

ACCOMPANYING LABELING: Leaflets entitled "Price List Effective March 1954."

LIBELED: On or about 9–23–54, Dist. Md.

CHARGE: 502 (a)—the accompanying labeling of the articles, when shipped, contained false and misleading representations that the articles would be effective for the poultry diseases designated as mycosis, enteritis (gizzard erosion), coccidiosis, chronic respiratory disease, air sac cold, and necro, and blackhead in turkeys.

DISPOSITION: 4–25–55. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4881 TO 4920

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4894) Injunction issued.

[1] (4894) Injunction issued.

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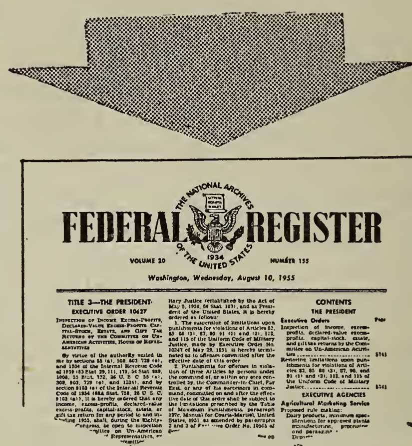
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TITLE 3—THE PRESIDENT

EXECUTIVE ORDER 10627

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THE PRESIDENT

Executive Orders

EXECUTIVE AGENCIES

The Federal Register publishes the full text of Presidential Proclamations and Executive Orders, and the rules and regulations of the various Departments of the Federal Government.

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4921–4960

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or summary judgment, and (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 11, 1957.*

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*For presence of a habit-forming narcotic without warning statement, see No. 4925; omission of, or unsatisfactory, ingredients statements, Nos. 4923, 4942; sale under name of another drug, Nos. 4926, 4939, 4940; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4923, 4925, 4942; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4923, 4925.

412734—57——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4921–4960

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia and National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, and its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, including the quantity of alcohol contained therein; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (g), the article purported to be a drug, the name of which is recognized in an official compendium, and it was not packaged as prescribed therein; Section 502 (i) (3), the article was offered for sale under the name of another drug; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4921. Sobrin and Solfera tablets. (F. D. C. No. 35126. S. Nos. 40–628 L, 44–420 L, 49–432 L, 52–320 L.)

INFORMATION FILED: 8–20–53, Dist. N. J., against Scientific Aids Co., a partnership, Jersey City, N. J., and George Van Dyne and Maurice Van Dyne, partners; amended information filed 3–5–54.

ALLEGED VIOLATION: The information alleged that, within the period from 6–10–52 to 8–25–52, while a quantity of *Solfera tablets* was being held for sale, the defendants repackaged a number of the tablets under labels which failed to bear adequate directions for use, which act resulted in the tablets being misbranded.

The information alleged also that, between 8–22–52 and 10–13–52, the defendants shipped misbranded *Solfera tablets* and *Sobrin* from New Jersey to Massachusetts, New York, and Washington.

LABEL IN PART: (Btl.) "Sobrin Emetic Brand of Fluid Extract of Ipecac Alcohol 31% ½ oz. Distributed by Scientific Aids Co. Box 118 Jersey City 3, N. J. Directions: Put 30 drops of this fluid into the first drink only. Do not use any more drops during the next 24 hours, no matter how many more drinks are taken following the first drink. Use only as directed above and by directions accompanying bottle. Caution: Do not use in heart, liver, pregnancy, kidney or circulatory disease without consulting your physician" and "Solfera Tablets Directions: Take one tablet with water after each meal three times daily. Caution: Use only as directed. Contents: Ferrous Sulphate—Each tablet contains 5 grains U. S. P. 50 Tablets Indicated for secondary Anemia when due to Iron Deficiency. Distributed By Scientific Aids Company, Inc. Box 118 Jersey City 3, N. J."

ACCOMPANYING LABELING: (*Sobrin*) Circulars entitled "Instructions in English" and "Read What Happy Satisfied People Write After Using Our Famous Formula and Method."

CHARGE: *Sobrin.* 502 (a)—the labeling of the article, when shipped by the defendants, contained false and misleading representations that the article was an adequate and effective treatment for drunkenness; and 502 (j)—the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling.

Solfera tablets. 502 (f) (1)—the labeling of the article, when shipped by the defendants and while held for sale by the defendants, failed to bear adequate directions for use for the purpose and condition for which it was intended, namely, for use in the treatment of persons suffering from delayed menstruation. The article was offered for that condition and purpose in magazine advertisements sponsored by the defendants.

DISPOSITION: On 9–9–53, the defendants entered pleas of not guilty. Thereafter, they filed motions to dismiss the information and to suppress evidence thereunder on the grounds (1) that the information was based on a statute that was confusing and ambiguous; (2) that the method by which the Government obtained its evidence precluded any criminal action against the defendants; (3) that the information was founded upon evidence illegally acquired in derogation of Section 703 of the Act and in violation of defendants' constitutional rights; (4) that the information violated defendants' privilege of immunity under Section 703; (5) that having secured the evidence used against defendants under a libel, it was unlawful for the Government to use that evidence in a criminal prosecution of defendants; and (6) that the matters alleged in the information were res adjudicata.

The above-mentioned motions came on for hearing before the court; and, on 1–19–54, the court, having determined that the grounds urged in support thereof were without merit, entered orders denying the motions. With respect to the motion to suppress evidence, the court, in an opinion reported in United States v. Scientific Aids Co., et al, 117 F. Supp. 588 (D. N. J. 1954), found that the inspections were made under Section 704 during the usual business hours without objection by the defendants who, at the inspector's request, voluntarily surrendered to him samples of their product, specimens of their labels, and copies of their advertising, and that the defendants made the pertinent records available and acquiesced in the inspectors' examination. The court further held that Section 703 was not applicable and that defendants' constitutional rights had not been violated.

On 3–5–54, the information was amended; and, on 4–9–54, the individual defendants entered pleas of guilty. Thereafter, on 5–28–54, the individual

defendants filed a motion for leave to withdraw their pleas of guilty and enter pleas of not guilty. This motion was denied on 7–13–54. On 8–11–54, the court fined each individual defendant $1,000 and sentenced each to imprisonment for 6 months. The court suspended this sentence and placed the defendants on probation for 2 years. The partnership was dismissed as a defendant upon the Government's motion at the time of sentencing.

On 8–20–54, the individual defendants filed a notice of appeal to the United State Court of Appeals for the Third Circuit; and, on 12–28–54, this court, after considering arguments and briefs of counsel, entered an order affirming the judgment of the lower court.

4922. Lady Bountiful device. (F. D. C. No. 38480. S. No. 36–961 M.)

QUANTITY: 179 individually cartoned devices at New York, N. Y.

SHIPPED: 9–3–55, from Hollywood, Calif., by Atlanta Corp.

ACCOMPANYING LABELING: A brochure entitled "The story of Lady Bountiful" and a circular designated "Lady Bountiful News November 22, 1951."

RESULTS OF INVESTIGATION: The device consisted of two rubber-edged plastic cups, one of which was slightly larger than the other, and a long rubber hose attached to a specially designed aspirator for attachment to the water faucet.

In use, the plastic cup would be pressed against the chest so that it enclosed one of the breasts and the rubber edge formed an air-tight seal against the chest. The small compact pump fitted over the cold water faucet; the cold water flowed through the specially designed pump and down the drain, never touching the breast but creating a controlled vacuum directed into the plastic cup. By applying and relaxing the thumb on the opening at the top of the rubber tube, the vacuum in the cup exercised the breast by contraction and relaxation.

LIBELED: 10–6–55, S. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped and while held for sale, contained false and misleading representations that the article was effective for increasing the size of the breasts, for providing shape, growth, and expansion for underdeveloped or sagging breasts so that they would become full, round, and firm; and for improving the tone of the breast tissues; and 502 (j)—the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling since the directions appearing therein recommended and suggested that the device be used from 10 to 25 minutes a day for a period of 2 or 3 months, whereas when used as recommended and suggested, the device may be dangerous where an unsuspected cancer is present or where other pathological conditions may be present.

DISPOSITION: 12–28–55. Default—portion delivered to Food and Drug Administration and remainder destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4923. H–17 and physiological salt solution. (F. D. C. No. 38421. S. Nos. 13–116/7 M.)

QUANTITY: 37 50-cc. vials of *H–17* and 37 50-cc. vials of *physiological salt solution* at Philadelphia, Pa.

SHIPPED: 5–10–55, from Los Angeles, Calif., by Rene Labhardt.

RESULTS OF INVESTIGATION: The *H–17* was represented by the shipper to contain alcoholic extract of *Radix gelsemii*, *Radix ononidis*, *Salix alba*, *Passiflora*, *Hydrastis*, formic acid, *Nerium* 0.00003 mgm., *Cannabis sativa* 0.00003 mgm., sodium gold chlorate 0.00003 mgm., and ergot 0.00003 mgm.

The vials of *physiological salt solution* were closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus, the contents of the vial could be withdrawn without removal or destruction of the closure. Such vials are classed as multiple dose containers under the definition set forth in the United States Pharmacopeia. Since the vials contained 50 cc. and the Pharmacopeia requires that no multiple dose container shall contain "a volume * * * more than sufficient to permit the withdrawal of 30 cc.," the article was not packaged in conformity with the pharmacopeial requirement.

LIBELED: 9–2–55, E. Dist. Pa.

CHARGE: 502 (b) (1) and (2)—when shipped, both articles failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; 502 (e) (2)—the label of the *H–17* failed to bear the common or usual name of each active ingredient; 502 (g)—the *physiological salt solution* purported to be a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein; and 505 (a)—the *H–17* was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 10–20–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4924. Nutrilite food supplement. (F. D. C. No. 37268. S. No. 89–515 L.)

INFORMATION FILED: 7–27–55, W. Dist. Wis., against Reuben L. Oschman, Platteville, Wis.

ALLEGED VIOLATION: On 8–5–54, the defendant, in the course of a sales talk to an individual, made oral representations that the article was an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the article being misbranded while held for sale.

LABEL IN PART: (Pkg.) "Nutrilite (R) XX Food Supplement This package contains multiple vitamin capsules and mineral tablets for use as a dietary food supplement to fortify, or supplement, the diet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, nervousness, rundown condition, arthritis, sinus trouble, asthma, high blood pressure, low blood pressure, heart trouble, back trouble, prostate gland trouble, headaches, rupture, lack of muscle tone, fatigue, diabetes, piles, stomach ulcers, and hardening of arteries.

PLEA: Guilty.

DISPOSITION: 9–23–55. $100 fine and probation for 1 year.

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*See also No. 4921.

4925. Pentobarbital sodium capsules. (F. D. C. No. 38518. S. No. 24–228 M.)

INFORMATION FILED: 12–13–55, N. Dist. Ill., against Louis F. Sladky, Chicago, Ill.

SHIPPED: 10–29–55, from Illinois to California.

CHARGE: 502 (b) (1) and (2)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of contents; 502 (d)—the article contained a chemical derivative of barbituric acid, which has been designated by regulations as habit forming, and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; and 502 (f) (1)—the labeling of the article bore no directions for use.

PLEA: Guilty.

DISPOSITION: 1–10–56. $500 fine, plus costs.

4926. Rauwolfia. (F. D. C. No. 37523. S. No. 4–305 M.)

QUANTITY: 4 drums of *No. 40 powdered Malabar Rauwolfia* root and 2,400 btls., 100 tablets each, of *Maxitate with Rauwolfia Comp.* at Rochester, N. Y., in possession of R. J. Strasenburgh Co.

SHIPPED: The powdered *Rauwolfia* was shipped in bulk drums on 11–19–53, by S. B. Penick & Co., New York, N. Y., from its New Jersey establishment.

LABEL IN PART: (Drum) "Grd. No. 40 Malabar Rauwolfia Root * * * Caution—For Manufacturing Processing Or Repacking * * * S. B. Penick & Co. New York Chicago"; (btl.) "Maxitate with Rauwolfia Comp. * * * Rauwolfia (whole root) 30 Mg. * * * R. J. Strasenburgh Co., Rochester, N. Y."

RESULTS OF INVESTIGATION: Upon receipt of the shipment of the powder, the consignee, who had an effective new drug application for drugs containing powdered *Rauwolfia serpentina* root, manufactured the *Maxitate with Rauwolfia Comp. tablets* from a portion of such powder. Examination showed that the article in powder and tablet form consisted in whole or in part of a species of *Rauwolfia* other than *Rauwolfia serpentina* and for which there was not an effective new drug application.

LIBELED: 12–10–54, W. Dist. N. Y.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement; and 502 (i) (3)—the article was a drug which was not *Rauwolfia serpentina* and was offered for sale under the name of another drug, *Rauwolfia serpentina.*

DISPOSITION: 3–21–55. Consent—claimed by R. J. Strasenburgh Co., Rochester, N. Y. The decree condemned the article and provided that it be released to the custody of the claimant for further investigation, with a view toward making application therefor as a new drug. The decree specified that the claimant could segregate and use no more than 10 lbs. of the powdered drug and 5,000 tablets for such investigational purposes, with the balance to be held by the claimant under bond until a new drug application regarding the article became effective.

After the claimant had found that it was impractical to continue its investigation, a stipulation was entered providing for the destruction of the remainder of the article. On 10–7–55, pursuant to the stipulation, an order was entered providing for the destruction of the drug.

4927. Amphetamine sulfate tablets. (F. D. C. No. 38281. S. Nos. 4–586/8 M.)

QUANTITY: 5 1,000-tablet btls., 1 500-tablet btl., and 1 50-tablet btl., at Vestal, N. Y.

SHIPPED: 7–18–55, from Youngstown, Ohio.

LIBELED: 8–15–55, N. Dist. N. Y.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use, and it was not entitled to any exemption from that requirement.

DISPOSITION: 10–15–55. Default—destruction.

4928. Dexadex tablets. (F. D. C. No. 38267. S. Nos. 21–656 M, 21–797 M.)

QUANTITY: 2 1,000-tablet btls. and 647 100-tablet btls. at Philadelphia, Pa., in possession of Cabot Pharmaceutical Co.

SHIPPED: 6–10–54, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Cabot * * * Tablets Dexadex (Formerly Dexadel) Each tablet contains Dextro-Amphetamine Sulfate 10 mg."

RESULTS OF INVESTIGATION: The tablets were shipped in bulk from Cleveland, Ohio, and upon their receipt by the consignee, they were repackaged and relabeled. Analysis showed that the article contained substantially less than the declared amount of dextro-amphetamine sulfate.

LIBELED: 8–3–55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; 502 (a)—the label statement "Each tablet contains Dextro-Amphetamine Sulfate 10 mg." was false and misleading; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its label failed to bear a statement of the recommended or usual dosage.

DISPOSITION: 9–29–55. Default—destruction.

4929. West-Lax tablets. (F. D. C. No. 38483. S. Nos. 29–593/4 M.)

QUANTITY: 1 10,000-tablet drum and 1 25,000-tablet drum and a number of empty boxes at East Orange, N. J., in possession of Olive May Co.

SHIPPED: 8–3–55 and 8–31–55, from Baltimore, Md., by Mineralized Foods, Inc.

LABEL IN PART: (Drum) "West-Lax A Good Laxative Consists of an imported variety of West's Sea Vegetation (Edible Sea Plants) naturally laxative, carefully blended with Senna Fruit, ripe fruit of Cassia Fistula and Chinese Rhubarb, flavored with Peppermint Leaves * * * Manufactured by Mineralized Foods Inc., Baltimore Maryland * * * The Contents Of This Drum Is Intended For Re-Packaging and Re-Labeling By The Consignee"; (box) "Tablets number 206 1.00 Olive May Co. * * * Dietary Supplement."

RESULTS OF INVESTIGATION: The consignee intended to repackage the article from the drums into the empty boxes.

LIBELED: 10–10–55, Dist. N. J.

CHARGE: 502 (a)—the statement "Dietary Supplement" borne on the box label of the article, while held for sale, was false and misleading since the article was not a dietary supplement and possessed no dietary properties; 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use; and 502 (f) (2)—the labeling of the article, when shipped and while held for sale, failed to bear a warning

against use in case of nausea, vomiting, abdominal pains, or other symptoms of appendicitis, and a warning that frequent or continued use may cause a dependency upon laxatives to move the bowels.

DISPOSITION: 11–17–55. Default—destruction.

4930. Devine's Zina-Ray oil, Devine's Na-Zol ointment, and Devine's inhaler. (F. D. C. No. 37787. S. Nos. 14–317/8 M.)

QUANTITY: 210 2-dram vials, 393 1-oz. btls., 330 3-oz. btls., and 70 8-oz. btls. of *Devine's Zina-Ray oil;* 253 1-oz. jars of *Devine's Na-Zol ointment;* and 2,873 *Devine's inhalers;* also 1 ⅛-oz. btl. of cough syrup made with *Devine's Zina-Ray oil;* 1 1-oz. vial containing menthol; 1 1-oz. vial containing gum camphor; 1 1-oz. vial containing eucalyptus oil; 1 plaster plaque model of cross-section of the human head; 1 box with outline of cross section of the human head showing air passages and sinuses; one section of arthritic human vertebras; and one cut-away demonstration of human skull, at St. Louis, Mo., in possession of Howard Dean, demonstrator for Devine's Remedies, Inc., of Chicago, Ill.

SHIPPED: 1–30–54 and 1–12–55, from Chicago, Ill.

RESULTS OF INVESTIGATION: Howard Dean, in the course of a sales talk, recommended the *Devine's Zina-Ray oil* and *Devine's Na-Zol ointment* for use in the treatment of the diseases and conditions described below.

Examination disclosed that the oil and ointment had the odor of eucalyptus, camphor, and menthol. The inhaler was intended for use with the oil.

LIBELED: 2–14–55, E. Dist. Mo.

CHARGE: 502 (f) (1)—the labeling of *Devine's Zina-Ray oil* and of *Devine's Na–Zol ointment,* while held for sale, failed to bear directions for use in the treatment of the conditions for which such articles were intended, namely, (oil) headache, hay fever, rose fever, sore throat, tonsillitis, bronchitis, asthma, infected sinuses, soft flabby gums, arthritis, rheumatism, swollen, sore, stiff joints, and (ointment) sore throat.

DISPOSITION: 10–5–55. Consent—claimed by Devine's Remedies, Inc. A placard entitled "Ethmoid Labyrinth" and the above-mentioned box, with its contents, were delivered to the Food and Drug Administration. The above-mentioned drugs, inhalers, and plastic cut-away model of the human head, together with leaflets entitled "Pain Sufferers," were released to the claimant and shipped to its place of business at Chicago, Ill.

4931. Uranium ore. (F. D. C. No. 38262. S. No. 21–050 M.)

QUANTITY: 275 pads packed with *ground uranium ore* and 1,000 lbs. of *loose uranium ore* at Gordon, Nebr., in possession of Mrs. Peggy Bartow, t/a Uranium Center.

SHIPPED: During July 1954, from Pacho, Ariz.

RESULTS OF INVESTIGATION: The *uranium ore* was shipped in bulk, and, after receipt by the consignee, a portion was packed into the pads. The *loose uranium ore* was contained in the backs and seats of full length benches and in the ceiling of a room designated "the sitting room," located in the building housing the Uranium Center.

The patient either sat or reclined on the uranium padded bench while undergoing the "treatment" provided by the purported radioactivity of the ore. The loose pads were provided the patient for placing over affected portions of the body while he was being "treated" in the sitting room.

The ore was found to possess small radioactivity. The sale of the pads and ore was promoted by sales presentations made by Mrs. Bartow and by a newspaper advertisement printed on Mrs. Bartow's instructions.

LIBELED: 8–3–55, Dist. Nebr.

CHARGE: 502 (f) (1)—the labeling of the ore and pads, while held for sale, failed to bear adequate directions for use in the treatment of arthritis, rheumatism, sinus conditions, and hemorrhoids, which were the conditions for which the articles were intended and for which they were offered in the above-mentioned advertisement and sales presentations.

DISPOSITION: 9–8–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4932. Sulfadiazine tablets. (F. D. C. No. 33782. S. No. 6–556 L.)

INFORMATION FILED: 8–16–54, E. Dist. N. Y., against Robin Pharmacal Corp., Brooklyn, N. Y., and Sidney Rich, president.

SHIPPED: 5–5–52, from New York to Massachusetts.

LABEL IN PART: (Btl.) "1000 Sulfadiazine Berkeley (2-Sulfanilamidopyrimidine) Compressed Tablets (Scored) 0.5 Gm. (7.7 Grains)."

CHARGE: 501 (b)—the strength of the tablets, when shipped, differed from the standard set forth in the United States Pharmacopeia for sulfadiazine tablets since the tablets contained less than 95 percent of the declared amount of sulfadiazine, the minimum permitted by the standard.

PLEA: Guilty.

DISPOSITION: 4–24–56. Corporation and individual each fined $1,000. Individual sentenced to imprisonment for 1 year; prison sentence suspended and individual placed on probation for 3 years.

4933. Vitamin Spheroids. (F. D. C. No. 38131. S. No. 2–573 M.)

INFORMATION FILED: 8–1–55, E. Dist. Mo., against Keith-Victor Pharmacal Co., a corporation, St. Louis, Mo.

SHIPPED: 12–3–54, from Missouri to Maryland.

LABEL IN PART: (Pkg.) "Sugar Coated Red Oval Nine Vitamin Spheroids Each Spheroid Contains: Vitamin B_6 Source Pyridoxine Hydrochloride Content 0.25 Mg."

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it was represented to possess, in that each spheroid of the article was represented to contain 0.25 milligram of pyridoxine hydrochloride (vitamin B_6), whereas each spheroid contained less than .05 milligram of pyridoxine hydrochloride.

PLEA: Nolo contendre.

DISPOSITION: 8–22–55. $500 fine, plus costs.

4934. Amobarbital sodium. (F. D. C. No. 38266. S. No. 17–585 M.)

QUANTITY: 66 vials at Lawrenceville, Va.

SHIPPED: 4–22–55, from Philadelphia, Pa., by Addison Laboratories.

LABEL IN PART: (Vial) "Amobarbital Sodium 7½ gr. Sterile — Intravenous * * * No. 6773."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to meet the test specified in the National Formulary regarding permissible variations in the weight of individual containers. Analysis showed also that the individual containers contained from 42 percent to 117 percent of the declared amount of amobarbital.

LIBELED: 8–5–55, E. Dist. Va.

CHARGE: 501 (b)—the article, when shipped, purported to be and was represented as "Sodium Amobarbital," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Amobarbital Sodium 7½ gr." was false and misleading.

DISPOSITION: 12–6–55. Default—destruction.

4935. Code #55 capsules. (F. D. C. No. 38097. S. No. 19–715 M.)

QUANTITY: 2 cartons, 7,850 capsules each, at Columbus, Ohio.

SHIPPED: 1–11–52 and 11–13–52, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than the declared amount of vitamin C (ascorbic acid).

LIBELED: 7–20–55, S. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 50 milligrams of vitamin C per capsule; and 502 (a)—the label statement "Ingredients in each capsule: * * * Ascorbic Acid U. S. P. 50 Mg." was false and misleading.

DISPOSITION: 8–25–55. Default—destruction.

4936. Moe Pap liquid. (F. D. C. No. 38101–A. S. No. 13–976 M.)

QUANTITY: 100 4-oz. btls. at Memphis, Tenn.

SHIPPED: 4–15–55 and 4–26–55, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 75 percent of the declared amount of vitamin B_1.

LIBELED: 7–25–55, W. Dist. Tenn.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1,500 I. U. of vitamin B_1 per fluid ounce; and 502 (a)—the label statement "Thiamine Hydrochloride (Vitamin B_1) 1500 I. U. per Fluid Ounce" was false and misleading.

DISPOSITION: 9–1–55. Default—destruction.

4937. Ala-Dyne tablets. (F. D. C. No. 38238. S. No. 29–309 M.)

QUANTITY: 1 1,000-tablet btl. and 608 100-tablet btls. at Emerson, N. J., in possession of Allied Drugs, Inc.

SHIPPED: 12–19–50 and 5–26–52, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Ala-Dyne Each Tablet Contains Acetylsalicylic Acid 4 grs. Calcium Glutamate 2 grs. Ascorbic Acid 30 mg. Allied Drugs, Inc. Hackensack, New Jersey Distributors Caution To be dispensed by or on the prescription of a physician. 2676 [or "4993"]."

RESULTS OF INVESTIGATION: The article was shipped in interstate commerce in bulk, and, upon receipt by the consignee, was repackaged. Analysis showed that lot number 2676 contained 76 percent of the labeled amount of acetylsalicylic acid.

LIBELED: 7–13–55, Dist. N. J.

CHARGE: (Btls. numbered 2676) 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; (all btls.) 502 (a)—the label statement "Caution To be dispensed by or on the prescription of a physician" was false and misleading since the statement represented that the article was a prescription drug, whereas it was not such a drug but was safe and suitable for sale without a prescription, and its label should have contained adequate directions for use.

DISPOSITION: 9–13–55. Default—destruction.

4938. Dormelix-B. (F. D. C. No. 38482. S. No. 3–678 M.)

QUANTITY: 15 cartons, 12 1-pt. btls. each, at Boston, Mass.

SHIPPED: Sometime during 1950, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 53 percent of the declared amount of vitamin B_1.

LIBELED: 10–5–55, Dist. Mass.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each Fluid Ounce Contains: * * * Vitamin B_1 * * * . . . . 3.0 mg. (1000 U. S. P. Units)" was false and misleading.

DISPOSITION: 12–5–55. Default—destruction.

4939. Rauwolfia serpentina (powder and tablets). (F. D. C. No. 37373. S. No. 13–086 M.)

QUANTITY: 1 65-lb. drum of the powdered drug, 420,000 uncoated and 35,000 coated 50-milligram tablets, and 100,000 uncoated and 70,000 coated 100-milligram tablets at Allentown, Pa.

SHIPPED: On 6–25–54, S. B. Penick & Co. shipped from Jersey City, N. J., a bulk lot of the drug in powder form.

LABEL IN PART: (Bulk drum) "Powdered Rauwolfia Serpentina Root."

RESULTS OF INVESTIGATION: The tablets were prepared by the consignee from a portion of the bulk powder in the above-mentioned shipment. Examination showed that the article in powdered form and in tablet form contained the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 12–1–54, E. Dist. Pa.

CHARGE: 501 (d) (2)—the article (in bulk and in tablet form), when shipped in the form of powder, was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part; 502 (a)—the designation "Rauwolfia Serpentina" borne on the drum label of the article, when shipped, was false and misleading since such designation represented and suggested that the article in the bulk drum consisted wholly of *Rauwolfia serpentina*, whereas such was not the case; and 502 (i) (3)—the article (in bulk and in tablet form), when shipped, was offered for sale under the name of another drug.

DISPOSITION: 8–3–55. S. B. Penick & Co. having appeared and later having withdrawn as claimant, judgment of condemnation was entered and the product was ordered destroyed.

4940. Rauwolfia serpentina. (F. D. C. No. 37503. S. No. 3–085 M.)

QUANTITY: 252 lbs. in 3 cases at Stamford, Conn.

SHIPPED: 8–17–54, from New York, N. Y., by Gane & Ingram.

LABEL IN PART: (Case) "R. S. Powder * * * Made in India."

RESULTS OF INVESTIGATION: Examination showed that the article contained a large amount of the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 12–9–54, Dist. Conn.

CHARGE: 501 (d) (2)—the article was a drug represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part when shipped; and 502 (i) (3)—the article was offered for sale under the name of another drug.

DISPOSITION: 4–10–56. Default—destruction.

4941. Nasal spray. (F. D. C. No. 38233. S. No. 29–323 M.)

QUANTITY: 288 20-cc. btls. at Newark, N. J.

SHIPPED: 6–15–55, from Brooklyn, N. Y., by Success Chemical Co., Inc.

LABEL IN PART: (Btl.) "R/W Tyro-Hist Nasal Spray Decongestant - Antihistamine Antibiotic * * * Contains In Aqueous Isotonic Solution: Tyrothricin . . . 0.02%."

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 1 percent of the declared amount of tyrothricin.

LIBELED: 7–12–55, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Contains In Aqueous Isotonic Solution: Tyrothricin. . . . 0.02%" was false and misleading.

DISPOSITION: 1–10–56. Default—destruction.

4942. Antiseptic solution. (F. D. C. No. 38684. S. No. 18–846 M.)

QUANTITY: 25 cases, 36 4-oz. btls. each, at Mansfield, Ohio.

SHIPPED: Between 1935 and 1954, from points outside the State of Ohio.

LIBELED: 11–18–55, N. Dist. Ohio.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess (the article contained less than 25 percent alcohol as declared on its label); 502 (b) (2)—the label statement "Contents 4 fl. ounces" was inaccurate (the article was short weight); and 502 (e) (2)—the label failed to bear a statement of the quantity of alcohol contained in the article.

The libel alleged that certain articles of food were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 12–15–55. Default—destruction.

4943. Clinical thermometers. (F. D. C. No. 38488. S. No. 17–250 M.)

QUANTITY: 252 *clinical thermometers* at Richmond, Va.

SHIPPED: 4–15–55, from Brooklyn, N. Y., by Cardinal Thermometer Co.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind — Oral."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Accuracy For Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 7 thermometers failed to comply with the requirement for accuracy specified in CS1–52 issued by the National Bureau of Standards of the Department of Commerce when tested as described in CS1–52.

LIBELED: 10–13–55, E. Dist. Va.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling accompanying the article, when shipped, were false and misleading since they were contrary to fact: "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce."

DISPOSITION: 1–4–56. Default—destruction.

4944. Clinical thermometers. (F. D. C. No. 38415. S. No. 29–817 M.)

QUANTITY: 204 *clinical thermometers* at Newark, N. J.

SHIPPED: 6–28–55, from New York, N. Y., by Emrose Thermometer Co.

LABEL IN PART: (Envelope) "Style Oral Stubby Emrose 'Medik-Aid' A Tested Clinical Thermometer * * * Accurate."

LIBELED: 9–7–55, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statements in the labeling of the article, namely, "We, the undersigned distributors hereby certify that this registering Clinical Thermometer marked E M has been examined and tested and found to meet all the requirements and tests specified in commercial standard, CS1–52," were false and misleading as applied to the article, which failed to meet the test for accuracy laid down in Commercial Standard CS1–52, issued by the United States Department of Commerce.

DISPOSITION: 10–11–55. Default—destruction.

4945. Clinical thermometers. (F. D. C. No. 38496. S. No. 29–999 M.)

QUANTITY: 189 *clinical thermometers* at Perth Amboy, N. J.

SHIPPED: 7–6–55 and 8–22–55, from Brooklyn, N. Y., by the Cardinal Thermometer Co.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind — Stubby."

ACCOMPANYING LABELING: Leaflet entitled "Certificate of Accuracy For Clinical Thermometer."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 4 thermometers failed to comply with the requirement for accuracy specified in CS1–52 issued by the National Bureau of Standards of the Department of Commerce when tested as described in CS1–52.

LIBELED: 10–13–55, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the following statements in the labeling accompanying the article, when shipped, were false and misleading since they were contrary to fact: "We, the undersigned

manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce."

DISPOSITION: 11–17–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

4946. Powdered extract of Veratrum viride and fluidextract of belladonna root. (F. D. C. No. 35199. S. Nos. 38–064 L, 38–066 L.)

INFORMATION FILED: 12–3–53, Dist. N. J., against Meer Corp., North Bergen, N. J., and Ellis Meer, president of the corporation.

SHIPPED: 10–18–52 and 1–26–53, from New Jersey to New York.

LABEL IN PART: (Drum) "20 Pounds Net Powdered Extract Veratrum Viride Poison each 100 grams of extract contains 5 grams of the total alkaloids of Veratrum Viride * * * Meer Corporation 318 West 46th Street New York"; (btl.) "One Pint Fluid Extract Belladonna Root N. F. IX * * * Meer Corporation 318 West 46th Street New York 36, N. Y."

CHARGE: 502 (a)—(*Veratrum viride*) the statement on the label of the article, when shipped, "each 100 grams of extract contains 5 grams of the total alkaloids of Veratrum Viride" was false and misleading in that each 100 grams of the article contained less than 5 grams of the total alkaloids of *Veratrum viride*; and (*belladonna root*) the statement on the label of the article, when shipped, "Fluid Extract Belladonna Root N. F. IX" was false and misleading in that the article did not conform to the requirements for "Belladonna Root Fluidextract," as specified in the 9th Edition of the National Formulary, an official compendium, since it yielded from each 100 cc. less than 405 milligrams of the alkaloids of *belladonna root*.

PLEA: Corporation—guilty to count of information relating to *fluidextract of belladonna root*; individual—nolo contendere to two counts of information relating to both articles.

DISPOSITION: 5–13–55. Each defendant fined $500.

4947. Keystone liniment and Keystone Blood & Kidney Remedy. (F. D. C. No. 37295. S. Nos. 64–763/4 L.)

QUANTITY: 6 1-pt. btls. of *Keystone liniment* and 10 1-pt. btls. of *Keystone Blood & Kidney Remedy* at Seattle, Wash.

SHIPPED: 6–29–54 and 9–8–54, from Portland, Oreg., by Keystone Laboratories.

LABEL IN PART: (Btl.) "Forward Club * * * Keystone Liniment—For Man or Beast Ingredients: Herbs and Organic Minerals External Use Only" and "Forward Club * * * Keystone Blood & Kidney Remedy Ingredients: Herbs And Organic Minerals Dose: Internal, One Ounce A Day."

ACCOMPANYING LABELING: Labels for the "Keystone Blood & Kidney Remedy," booklets designated "Forward Ecclesiastic * * * Volume 3 1954 Number 39," and leaflets designated "Copy Of A Letter From A Member Written July 9, 1954."

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*See also Nos. 4921, 4922, 4928, 4929, 4934–4939, 4941, 4943–4945.

LIBELED: 10-14-54, W. Dist. Wash.

CHARGE: *Keystone liniment.* 502 (a)—the label contained false and misleading representations that the article was effective for overcoming bleeding, pain, infection, and fever.

Keystone Blood & Kidney Remedy. 502 (a)—the bottle label and the accompanying labeling contained false and misleading representations and suggestions that the article was an effective treatment for cleaning out the urinary canal, expelling gravel from the bladder, killing and expelling worms, increasing the menstrual flow, relieving pain, expelling phlegm from the lungs, purifying the blood, overcoming kidney ailments, chronic liver and gallbladder trouble, and diabetes.

The articles were misbranded when shipped and while held for sale.

DISPOSITION: On 3-4-55, Keystone Laboratories, Portland, Oreg., and Forward Club, Seattle, Wash., claimants, filed an answer denying that the articles were misbranded as alleged. Thereafter, interrogatories were served upon the claimants by the Government. The claimants withdrew their answer; and, on 12-16-55, the court entered a default decree condemning the articles and ordering that they be delivered to the Food and Drug Administration.

4948. Colusa tablets, Colusa liquid, and Colusa ointment. (F. D. C. No. 38200. S. Nos. 6-676/9 M.)

QUANTITY: 8 200-tablet btls. and 9 100-tablet btls. of *Colusa tablets;* 25 2-oz. btls. and 16 4-oz. btls. of *Colusa liquid;* and 9 3-oz. jars of *Colusa ointment,* at Dayton, Ohio.

SHIPPED: Between 1-31-55 and 6-15-55, from Los Angeles, Calif., by J & J Remedy Co.

LABEL IN PART: (Btl.) "Colusa Vitamin A Fortified Tablets (For Internal Use) As a dietary supplement. Containing Vitamin A Concentrate from fish liver oils, with a solidified petroleum base. Contains Phosphorus and Calcium. Each tablet contains 5000 U. S. P. Units of Vitamin A, which is 125% of the minimum daily adult requirement," and "Colusa A preparation for the relief of simple skin irritations, or where itching of the skin is caused by crustations, chapping and cracking. Also for use on dressings for minor cuts, abrasions and burns. Active-Ingredients Salicylic Acid, Methyl Salicylate and ½% Carbolic Acid (Phenol) in an Unrefined Petroleum oil base"; (jar) "Colusa Ointment A preparation for the relief of simple skin irritations, also for cuts, abrasions and burns. Also for relief of pain and itching due to Piles and Hemorrhoids * * * Active Ingredients * * * Zinc oxide, Benzocain, Menthol, Camphor, Lanolin, Yellow Bees Wax, Salicylic acide, ½% Phenol (carbolic acid) in an unrefined Petroleum oil base."

ACCOMPANYING LABELING: Placards designated "Skin Sufferers Quick Relief Get Fast Acting Colusa Today!"; leaflets entitled "Colusa What It Is And How To Use It"; pamphlets entitled "Colusa Products"; and proof sheets entitled "Skin Sufferers Quick Palliative Relief * * * With Fast Acting Colusa * * * Look at this Hand!" and "Skin Sufferers Quick Relief [or "Quick Palliative Relief"] * * * Keep Your Eyes On Results."

LIBELED: 6-29-55, S. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for eczema, psoriasis, scabies, skin rashes, and skin troubles of all kinds.

DISPOSITION: 8–15–55. Default—destruction.

4949. Mild laxative tablets with bile salts. (F. D. C. No. 37969. S. No. 6–037 M.)

QUANTITY: 984 display cartons, each containing 12 btls., at Chattanooga, Tenn., in possession of Eagle Products Co., Inc.

SHIPPED: 10–1–54, from St. Louis, Mo.

LABEL IN PART: (Display carton) "Eagle's Mild Laxative With Bile Salts * * * 1 Dozen * * * 35¢ Size"; (btl.) "20 Tablets * * * Eagle's Mild Laxative Tablets With Bile Salts Each Tablet Contains: Bile Salts Compound, Phenolphthalein, Extract Cascara Sagrada, Aloin and Podophyllin. As a laxative to aid in relieving temporary or occasional constipation. Sole Distributor Eagle Products Company, Inc. Chattanooga, Tennessee."

ACCOMPANYING LABELING: Leaflet entitled "Eagle's Mild Laxative Tablets With Bile Salts."

RESULTS OF INVESTIGATION: The article was shipped in bulk from St. Louis, Mo.; and, after receipt by the consignee, it was repackaged and relabeled.

LIBELED: 5–13–55, E. Dist. Tenn.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for various disorders of the liver and gallbladder and for chronic constipation.

DISPOSITION: 6–22–55. Consent—claimed by Eagle Products Co., Inc. The leaflets accompanying the article were destroyed.

4950. Crunchies. (F. D. C. No. 38499. S. Nos. 11–638/9 M.)

QUANTITY: 4 drums, each containing 25,000 *Crunchies*, and 3 drums, each containing 20,000 *Crunchies*, at Birmingham, Ala.

SHIPPED: 4–9–54, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained about 50 percent of the declared amount of vitamin D.

LIBELED: 10–12–55, N. Dist. Ala.

CHARGE: 502 (a)—the label statements of the article, while held for sale, namely, "Each 3 Crunchies Contain: * * * Vitamin * * * D . . . . Activated Ergosterol * * * 800 USP," was false and misleading as applied to a product which contained less than the stated amount of vitamin D.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 11–15–55. Default—destruction.

4951. Pan-Ascorin capsules. (F. D. C. No. 37907. S. Nos. 7–433/4 M.)

QUANTITY: 27 100-capsule btls. and 63 40-capsule btls. at Denver, Colo.

SHIPPED: 1–25–55 and 2–21–55, from Holland, Mich., by De Pree Co.

LABEL IN PART: (Btl.) "Pan Ascorin De Pree Providing therapeutic levels of vitamins associated with the health and function of the adrenal cortex * * * Each capsule provides: Ascorbic Acid (Vitamin C) 250 mgs. Riboflavin (Vitamin B_2) 5 mgs. Pantothenic Acid 100 mgs. * * * The Full Potency 'Stress' Vitamin Formula."

ACCOMPANYING LABELING: Leaflets designated "Pan-Ascorin The full-strength 'Stress' Vitamin Formula"; a poster entitled "Is STRESS the Cause of All

Disease? * * * Pan-Ascorin * * * Sold Here"; a window flyer entitled "Pan-Ascorin Full-Strength Formula 'Stress Vitamins'"; and a newspaper tear sheet containing an advertisement designated "Is STRESS the Cause of ALL Disease? * * * Pan-Ascorin * * * Get It At The U. S. Cut-Rate Drug Co." and prepared from a mat furnished by De Pree Co.

LIBELED: 3–31–55, Dist. Colo.

CHARGE: 502 (a)—the labeling of the article when shipped, contained false and misleading representations that the article was effective in the prevention and treatment of arthritis, rheumatism, rheumatic fever, allergies, exhausting physical exertion, severe injuries, burns, infections, toxic reactions, continued emotional, psychic, and nervous pressures, anaphylactic reactions, hay fever, and asthma; and that it was effective to increase resistance to the effects of all injuries and diseases of the human body and to insure the health and normal functioning of the adrenal glands.

DISPOSITION: On 5–16–55, De Pree Co. appeared as claimant and filed an answer denying that the article was misbranded as alleged. On 9–8–55, pursuant to a stipulation entered into by the parties, the court entered an order transferring the case to the Eastern District of Michigan for trial. Thereafter, the Government served interrogatories upon the claimant. The claimant withdrew its answer; and, on 2–17–56, the court entered an order of default providing for the forfeiture of the goods to the United States. The goods were destroyed.

4952. **Herb health tea.** (F. D. C. No. 37895. S. No. 5–288 M.)

QUANTITY: 96 cartons at Green Bay, Wis., in possession of Wm. M. Horner Co.

SHIPPED: 5–4–53, from Chicago, Ill.

LABEL IN PART: (Carton) "Wm. M. Horner's Pure Herb Health Tea * * * Made from roots, barks and leaves * * * Net Weight 5 Oz. When Packed."

ACCOMPANYING LABELING: Circular designated "Wm. M. Horner Co. * * * Pure Herb Family Remedies."

RESULTS OF INVESTIGATION: The article was shipped in bulk from Chicago, Ill.; and, after its receipt by the consignee, it was repackaged and relabeled. The above-mentioned circulars were printed for the consignee.

Examination showed that the article contained senna leaves, uva ursi, fennel seed, anise seed, licorice, elder flowers, and other plant material (unidentified).

LIBELED: 3–21–55, E. Dist. Wis.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for rundown conditions, tired feeling, constipation, stomach trouble, kidney, liver, and bladder trouble, coughs, colds, lung trouble, female disorders, skin diseases, and high blood pressure; and that it would strengthen the whole system, producing a clear healthy complexion.

DISPOSITION: 9–15–55. Default—destruction.

4953. **Mineral water.** (F. D. C. No. 38424. S. No. 4–379 M.)

QUANTITY: 50 cases, 12 btls. each, at Rochester, N. Y.

SHIPPED: 7–5–55, from Wyoming, Pa., by Crownhill Laboratories of Pennsylvania, Inc.

LABEL IN PART: (Btl.) "1 Quart Crownhill Farms * * * Mineral Water Fortified With Minerals Calcium Bicarbonate, Calcium Sulfate, Magnesium Chloride, Sodium Phosphate And Silica. For A Good Healthful Drink, 4 Oz. Morning And Night Is Sufficient."

ACCOMPANYING LABELING: Copies of letters from the shipper dated 6–24–55 and 7–18–55 and copies of suggested ads enclosed with the letter of 7–18–55.

LIBELED: 9–2–55, W. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for overcoming the pains of arthritis.

DISPOSITION: 10–31–55. Default—destruction.

4954. D'Velope. (F. D. C. No. 38470. S. No. 9–779 M.)

QUANTITY: 63 jars at Sioux City, Iowa.

SHIPPED: 8–25–55, from Chicago, Ill., by Daniels Pharmacal Co.

LABEL IN PART: (Jar) "One Month's Supply D'Velope Cream Formula for the Breast This jar contains 15,000 international units of natural estrogenic hormone (estrone) with histamine dihydrochloride and a special base. * * * Net weight 3 Oz."

ACCOMPANYING LABELING: Leaflet entitled "Directions For Using D'Velope Cream Formula" and a copy of an advertisement relating to the article, which appeared in a local newspaper.

RESULTS OF INVESTIGATION: The above-mentioned leaflet was attached to the lid of each jar. The above-mentioned newspaper advertisement had been printed on instructions of, and from a mat furnished by, the shipper, and a copy of the advertisement was on display on a counter in the consignee's store.

LIBELED: 9–30–55, N. Dist. Iowa.

CHARGE: 502 (a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was effective for developing the female breast.

DISPOSITION: 11–5–55. Default—destruction.

4955. Meredith's Pile Driver. (F. D. C. No. 37999. S. No. 19–059 M.)

QUANTITY: 6 cases, 12 cartoned tins each, at Johnson City, Tenn.

SHIPPED: 9–3–54 and 2–11–55, from Virginia Beach, Va., by Meredith Drug Co.

LABEL IN PART: (Carton) "Meredith's Pile Driver * * * Active Ingredients: Tannic Acid, Hebane, Menthol, Camphor & Carbolic Acid 1% Net. Wt. ⅜ Oz."

ACCOMPANYING LABELING: Leaflet entitled "Meredith's Pile Driver Ointment."

LIBELED: 6–1–55, E. Dist. Tenn.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for piles, old sores, felons, boils, sore nipples, bunions, and all other skin diseases.

DISPOSITION: 7–14–55. Default—destruction.

4956. Uranium ore and uranium comforter. (F. D. C. No. 38474. S. No. 35–986 M.)

QUANTITY: 1 200-lb. drum of *crushed uranium ore*, 1 170-lb. drum of *pulverized uranium ore*, and 1 50-lb. drum containing a *mixture of sand and pulver-*

ized uranium ore; 3 *cotton pads* measuring 8" x 13" packed with a mixture of sand and pulverized uranium ore; and 950 empty 8" x 13" cotton pads, at La Salle, Ill., in possession of C. A. Mazzuchelli, t/a Gra-Maze.

SHIPPED: 11–13–54, from Salt Lake City, Utah.

LABEL IN PART: (Pad) "Gra-Maze Uranium Comforter This Is Your Personal Radioactive Uranium Comforter. Actually Your Own Health Mine In Miniature. Guaranteed To Contain Radioactive Uranium Oxide. Can Be Checked By Geiger Counter. Distributed By Gra-Maze Box 457 La Salle, Ill."

ACCOMPANYING LABELING: Circulars entitled "Now The Gra-Maze Uranium Comforter."

RESULTS OF INVESTIGATION: The ore contained in the 8" x 13" pads had been shipped in bulk and repacked by the consignee. The above-mentioned circulars were printed for the consignee.

Examination showed that the ore (bulk and repackaged material) was slightly radioactive.

LIBELED: 9–30–55, N. Dist. Ill.

CHARGE: 502 (a)—the pad label and the circular accompanying the article, while held for sale, contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, sinusitis, and aching back, arms, legs, and joints, etc., and that it would produce good health.

DISPOSITION: 10–21–55. Default—destruction.

DRUGS FOR VETERINARY USE

4957. Blake's Mineral Compound (2 seizure actions). (F. D. C. Nos. 36836, 36837. S. Nos. 85–744 L, 85–755 L.)

QUANTITY: 11 pkgs. at Greybull, Wyo., and 18 pkgs. at Buffalo, Wyo.

SHIPPED: Between 6–22–53 and 4–23–54, from Denver, Colo., by Hy-Life Mineral Co. and Dencolo Corp.

LABEL IN PART: (Pkg.) "Blake's Mineral Compound * * * Ingredients: (active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder. * * * Net contents—3½ lbs. * * * Mix entire contents of this package (3½ lbs.) with 100 lbs. of * * * salt."

ACCOMPANYING LABELING: (18-pkg. lot) A circular entitled "For Sheep and Cattle pasturing in green alfalfa and clover meadows feed Blake's Mineral Compound."

LIBELED: 6–23–54, Dist. Wyo.

CHARGE: 502 (a)—when shipped, the statement on the package labels "A chemical preparation which, when mixed with salt as directed, is designed for feeding Sheep and Cattle while pasturing in green Alfalfa, Clover, or in Corn and Wheat fields. * * * 1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * REMOVE ALL OTHER SALT FROM YOUR LIVESTOCK. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter" and the statements in the accompanying labeling of the 18-package lot were false and misleading in that such statements represented and suggested that the article was effective in treating and preventing bloat and the effects of poison weeds in sheep and cat-

tle, whereas the article was not effective for such purposes; and, further, the name "Blake's Mineral Compound," the representation that the declared ingredients were active, and the following directions for use, appearing on the package labels, "1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * REMOVE ALL OTHER SALT FROM YOUR LIVESTOCK. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter. 2. When grain is fed—for example, to dairy cows—mix one 3½ lb. package of Blake's Mineral Compound with ONLY 15 LBS. OF FINELY GROUND SALT. Use this mixture to season the grain. Allow from one to two level tablespoons per head for cattle, or two level teaspoons per head for sheep. In addition to treating the grain ration when one is fed, be certain also to have the mixture described in paragraph one (above) available in troughs" were false and misleading. Such name, representation, and directions suggested that the article would furnish essential minerals required by sheep and cattle, whereas ammonium chloride and sodium sulfate are not required by sheep and cattle; tobacco powder is not a mineral; and the article, when used as directed, would furnish inconsequential nutritional amounts of potassium chlorate and calcium carbonate.

DISPOSITION: On 7–23–54, Dencolo Corp. and Harvey Rosenbaum, t/a Hy-Life Mineral Co., filed answers denying that the article was misbranded as alleged. On 3–11–55, the Government filed a motion for a summary judgment, which the court, after consideration of arguments and statements of counsel, granted on 2–8–56, handing down the following findings of fact and conclusions of law:

KERR, *District Judge:* "These causes having come on for hearing on February 7, 1956 on Libellant's Motion for Summary Judgment, the Libellant appearing by John F. Raper, Jr., United States Attorney, and the claimants appearing by Walter B. Phelan, their attorney, and the Court after considering the pleadings, affidavits and arguments of counsel makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

"1. The articles seized in these actions consist of a number of packages of a drug, the main ingredients of which are calcium carbonate, sodium sulphate, potassium chlorate, ammonium chloride and tobacco powder.

"2. The articles were manufactured in Colorado by Harvey Rosenbaum, doing business as Hy-Life Mineral Company in Denver, Colorado, and shipped in interstate commerce from Denver, Colorado to Buffalo, Wyoming and Greybull, Wyoming by the Dencolo Corporation of Denver, Colorado on or about June 23, 1953 and April 23, 1954; that both of said parties are the claimants in these actions.

"3. When introduced into and while in interstate commerce the labeling of the articles consisted of the following:

> (Pkg.) Blake's Mineral Compound * * * Ingredients: (active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder. * * * Net contents—3½ lbs. * * * Mix entire contents of this package (3½ Lbs.) with 100 lbs. of * * * salt * * * Hy-Life Mineral Co. 2139 Blake St. Denver, Colo.

"4. The article was intended for use in the treatment of bloat in sheep and cattle.

"5. When introduced into and while in interstate commerce the labeling of the article did not state that the article was intended to treat 'bloat', nor did it bear any directions for use in treatment of that disease.

"6. When introduced into and while in interstate commerce, and while held for sale, the following statements appeared on each package label:

> A chemical preparation which, when mixed with salt as directed, is designed for feeding sheep and cattle while pasturing in green alfalfa, Clover or in Corn and Wheat fields. * * *
>
> 1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * REMOVE ALL OTHER SALT FROM YOUR LIVESTOCK. Place this mixture in troughs conveniently accessible to livestock.
>
> Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter.

"7. The statements contained on the labels suggest and imply that the article is effective in the prevention and treatment of bloat in sheep and cattle.

"8. This Court in United States v. Ten Cartons * * * Blake's Stop-Bloat Chemicals, No. 2960 Civil, decided March 11, 1946, after a trial on the merits, that an article made up of the same components as that of the articles under seizure, was misbranded when it was offered as an effective treatment for bloat in livestock.

"9. The products 'Blake's Stop-Bloat Chemicals' and Blake's Mineral Compound involved in this and the previous action have substantially the same composition. The small quantitative differences in the composition would cause no difference in their effect upon sheep or cattle.

"10. The Claimant Hy-Life Mineral Company in this case was the same Claimant in Case No. 2960, though the owner at that time was J. P. Rosenbaum and the present owner is Harvey Rosenbaum. That the same issue involving the same parties has also been adjudicated in the District of Idaho in an action entitled United States v. 14 105 Pound bags, etc., cited in 118 F. Supp. 837, the Court there holding the matter res judicata by reason of District of Wyoming No. 2960.

"11. No genuine issue of material fact exists between the parties.

CONCLUSIONS OF LAW

"1. The seized article is a drug within the meaning of 21 USCA Section 321 (g) (2).

"2. The article of drug was shipped in interstate commerce.

"3. The drug was misbranded within the meaning of 21 USC 352 (a), in that such statements represent and suggest that the article is effective for treating and preventing bloat in sheep and cattle, whereas the article is not effective for such purposes.

"4. The Claimants are estopped by the principle of res judicata from contesting the issue as to whether the drug is effective in treating or preventing bloat in livestock, this issue having been decided adversely to them in prior litigation.

"5. The drug was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 USCA Section 352 (a), in that the statements in its labeling which recommended it for prevention, treatment or cure of bloat in sheep and cattle are false and misleading.

"6. The Libellant is entitled to summary judgment as a matter of law since there exists no genuine issue as to any material fact.

"To all of which the Claimants duly except, which exceptions are by the Court allowed."

On 2–8–56, the court entered a decree of condemnation and ordered that the article be destroyed.

4958. Cattle mineral, hog mineral, and stock tonic. (F. D. C. No. 38430. S. Nos. 18–819/20 M, 18–822 M.)

QUANTITY: 8 bags of *cattle mineral*, 9 bags of *hog mineral*, and 16 bags of *stock tonic* at New Philadelphia, Ohio.

SHIPPED: 7–27–55, from Roaring Spring, Pa., by Young's Stock Food Co.

LABEL IN PART: *Cattle mineral.* (Bag) "50 lbs. net Young's * * * Cattle Mineral Fortified with Vitamins A and D"; (tag) "Guaranteed Analysis Calcium 22.00% Phosphorus 17.00% Iodine 0.02% Salt None Drugs None Ingredients Precipitated Bone Phosphate, Monocalcium Phosphate, Magnesium Carbonate, Potassium Iodine, Iron Oxide, Iron Sulfate, Copper Sulfate, Cobalt Sulfate, Zinc Sulfate, Manganese Sulfate, Vitamin A Feeding Oil, D—Activated Plant Sterol (source of Vitamin D_2) Natural Flavors Added."

Hog mineral. (Bag) "50 Lbs. net Young's * * * Hog Mineral Fortified with Vitamins A and D"; (tag) "Guaranteed Analysis Calcium 23.00% Phosphorus 16.00% Iodine 0.02% Salt None Drugs None Ingredients Dicalcium Phosphate, Monocalcium Phosphate, Magnesium Carbonate, Potassium Iodine, Iron Sulfate, Iron Oxide, Manganese Sulfate, Monohydrate, Zinc Sulfate, Vitamin A Feeding Oil, D—Activated Plant Sterol (source of Vitamin D_2)."

Stock tonic. (Bag) "50 lbs. net Young's * * * Old Prescription Stock Tonic and Mineral Supplement"; (tag) "Guaranteed Analysis not less than Calcium 17.00% Phosphorus 13.00% Iodine 0.10% Salt None Vitamin D_2 75,000 U. S. P. units per pound Ingredients Foengreek, Licorice Root, Poke Root, Fennel Seed, Nux Vomica (minimum strychnine content .017%), Precipitated Bone Phosphate, Monocalcium Phosphate, Iron Oxide, Magnesium Carbonate, Potassium Iodide, Copper Sulfate, Cobalt Sulfate, Zinc Sulfate, Manganese Sulfate, Molasses, Distillers Dried Solubles, D—Activated Plant Sterol (source of Vitamin D_2)."

ACCOMPANYING LABELING: Pamphlets designated "Breeding Record Book" and leaflets designated "Are Your Cattle Being Held Back?" "Would you like to make hog production more profitable," and "You Asked For It."

LIBELED: 9–9–55, N. Dist. Ohio.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the *cattle mineral* was adequate and effective for treating and preventing bowel trouble, udder trouble, breeding and freshening problems, breeding disorders, rundown conditions, fall slump, calving problems, digestive disorders, and irregular heat periods, and that it would eliminate disease in general; that the *hog mineral* was an adequate and effective treatment for lameness, stiffness, and swollen joints, that it would make hogs stronger, healthier, and gain weight faster, and that it would produce more and stronger hogs at birth; and that the *stock tonic* was an adequate and effective treatment for stimulating the appetite, aiding digestion, increasing milk production, reducing breeding troubles, purifying the blood, providing better health and vigor, and providing healthier offspring.

DISPOSITION: 10–24–55. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO COMPLY WITH PACKAGING REQUIREMENTS OF AN OFFICIAL COMPENDIUM*

4959. Physiological saline solution. (F. D. C. No. 37091. S. No. 68–719 L.)

QUANTITY: 214 vials at Brooklyn, N. Y.

SHIPPED: 7–21–54, from Baltimore, Md., by Bio-Ramo Drug Co., Inc.

LABEL IN PART: (Vial) "100 cc. Single Dose Vial Physiological Saline Solution U. S. P. Sodium Chloride 0.9% W/V * * * Caution Contains no preservative."

*See also No. 4923.

RESULTS OF INVESTIGATION: Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 9–16–54, E. Dist. N. Y.

CHARGE: 502 (g)—the article purported to be a drug, namely, "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" packaged in multiple-dose containers.

DISPOSITION: Bio-Ramo Drug Co., Inc., claimant, filed an answer on 11–17–54, denying that the article was misbranded. Thereafter, the Government served interrogatories upon the claimant which were answered. On 8–31–55, with the consent of the claimant, judgment of condemnation was entered and the product was ordered destroyed.

4960. Water for injection. (F. D. C. No. 37080. S. No. 77–171 L.)

QUANTITY: 700 vials at Philadelphia, Pa.

SHIPPED: 7–15–54, from Baltimore, Md., by Bio-Ramo Drug Co., Inc.

LABEL IN PART: (Vial) "100 cc. Single Dose Vial Water For Injection U. S. P. * * * Manufactured by Bio-Ramo Drug Co., Inc. Baltimore 1, Md. Caution Contains no preservative."

RESULTS OF INVESTIGATION: Each vial was closed by a rubber stopper which could be readily penetrated by the ordinary hypodermic needle; thus the contents of the vial could be withdrawn without removal or destruction of the closure.

LIBELED: 10–1–54, E. Dist. Pa.

CHARGE: 502 (g)—the article purported to be a drug, namely, "Water for Injection," the name of which is recognized in the United States Pharmacopeia, an official compendium, and it was not packaged as prescribed therein (1) in that the article was packaged in a multiple-dose container containing a volume of the article more than sufficient to permit the withdrawal of 30 cc., whereas the United States Pharmacopeia prescribes that no multiple-dose container in which "Water for Injection" is packaged shall contain a volume more than sufficient to permit the withdrawal of 30 cc., and (2) in that the article was packaged in a multiple-dose container without the addition of a suitable substance or mixture of substances to prevent the growth of micro-organisms, whereas the United States Pharmacopeia prescribes that a suitable substance or mixture of substances to prevent the growth of micro-organisms must be added to "Water for Injection" packaged in multiple-dose containers.

DISPOSITION: On 11–3–54, pursuant to agreement of the claimant, Bio-Ramo Drug Co., Inc., and the Government, an order was entered for the removal of the case to the Eastern District of New York. On 8–31–55, with the consent of the claimant, judgment of condemnation was entered and the product was ordered destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4921 TO 4960

PRODUCTS

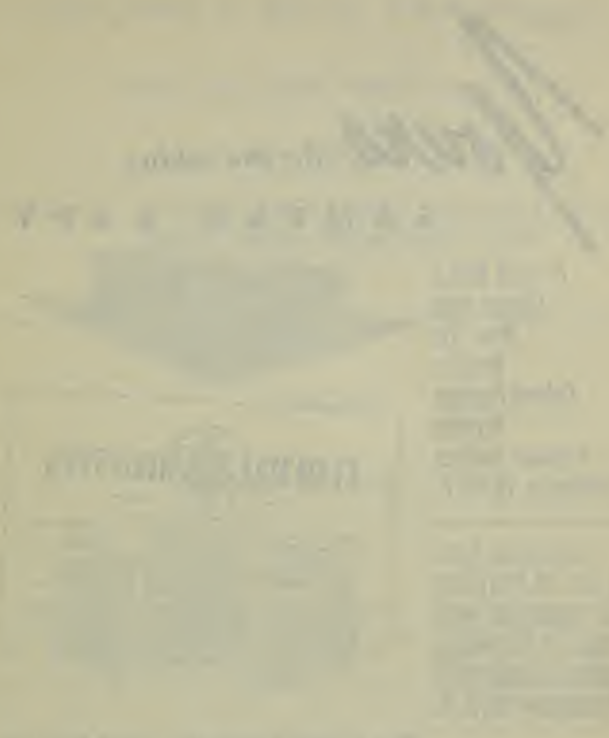
[1] (4957) Seizure contested. Contains findings of fact and conclusions of law.
[2] (4921) Prosecution contested.
[3] (4959) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4957) Seizure contested. Contains findings of fact and conclusions of law.
[3] (4959) Seizure contested.

[2] (4921) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1957



D. D. N. J., F. D. C. 4961–4980 Issued March 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4961–4980

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement, "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 1, 1957.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

4961. (F. D. C. No. 37–262. S. Nos. 14–205 M, 14–231 M, 14–238 M.)

INDICTMENT RETURNED: 9–1–55, E. Dist. Ark., against **Jack I. Lipson (manager of Owl Drug Store), West Memphis, Ark.**

CHARGE: Between 12–19–54 and 1–6–55, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 4–30–56. $1,000 fine and probation for 3 years.

4962. (F. D. C. No. 38161. S. Nos. 1–682/4 M, 1–686/7 M.)

INFORMATION FILED: 10–25–55, S. Dist. Ga., against **Jones Truck Stop (a partnership), 1 mile south of Folkston, Ga., and Troy E. Jones (a partner), and Robert Franklin Phillips and Betty Crews (employees).**

CHARGE: Between 5–6–55 and 5–10–55, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty—by Jones Truck Stop and Jones to all counts, by Crews to count 3, and by Phillips to count 4.

DISPOSITION: 4–30–56. Partnership and Jones fined $1,000 jointly and placed on probation for 2 years; Crews and Phillips each fined $50 and placed on probation for 2 years.

4963. (F. D. C. No. 38537. S. Nos. 22–251/2 M, 22–255/6 M.)

INFORMATIONS FILED: 10–24–55, N. Dist. Ind., against **Leon Poyser, t/a Black and White Motel and Restaurant, U. S. Highways 30 and 33, Fort Wayne, Ind., and Carol E. Arnoldy and Dolores Kimmerly (alias Kenney) (employees).**

10–29–55, N. Dist. Ind., against **Helen Brillhart (employee of Black and White Motel and Restaurant).**

CHARGE: Between 8–18–55 and 9–13–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty—by Poyser to dispensing the tablets 3 times and by each of the other individuals to dispensing the tablets once.

DISPOSITION: 12–5–55. Poyser fined $500, plus costs, and each of the other individuals fined $10, plus costs.

4964. (F. D. C. No. 38157. S. Nos. 4–773 M, 4–778 M, 5–122/4, 5–736 M.)

INFORMATION FILED: 10–5–55, N. Dist. Ill., against **Roth-Whipple Drug Store, Inc., Crystal Lake, Ill., Charles H. Matteo (vice president, manager, and pharmacist), James J. Corirossi (apprentice pharmacist), and Joseph H. Hewins (assistant pharmacist).**

CHARGE: Between 12–13–54 and 2–7–55, *Dexedrine Sulfate tablets* (counts 1 and 4) were dispensed twice and *dextro-amphetamine sulfate tablets* (count 2), *Pentids tablets* (count 3), *Pondets troches* (count 6), and *Gantrisin tablets* (count 5) were each dispensed once without a prescription.

PLEA: Nolo contendere—by the corporation to all counts, by Matteo to counts 3 and 4, by Corirossi to counts 1, 2, and 6, and by Hewins to count 5.

DISPOSITION: 11–28–55. Corporation fined $200, plus costs; Matteo fined $200; and Corirossi and Hewins each fined $100.

4965. (F. D. C. No. 38575. S. Nos. 26–562 M, 26–565 M, 26–567 M.)

INFORMATION FILED: 2–8–56, N. Dist. Iowa, against **John L. Schulte, t/a Schulte Drug Store, Sioux City, Iowa.**

CHARGE: Between 7–27–55 and 9–6–55, *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 2–8–56. Defendant sentenced to imprisonment for 6 months; prison sentence suspended and defendant placed on probation for 30 months.

4966. (F. D. C. No. 38553. S. Nos. 30–174 M, 30–180 M, 30–610 M.)

INFORMATION FILED: 11–29–55, E. Dist. Ill., against **Henry A. Buerkle, t/a Buerkle Drugs, West Frankfort, Ill.**

CHARGE: Between 8–2–54 and 8–10–54, *Dexedrine Sulfate tablets, Dexedrine Sulfate capsules,* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–7–55. Defendant fined $200, plus costs, and placed on probation for 1 year.

4967. (F. D. C. No. 38555. S. Nos. 30–171 M, 30–235 M, 30–603 M, 30–606/7 M.)

INFORMATION FILED: 12–16–55, E. Dist. Ill., against **Carl Barker, t/a Barker Drug Co., West Frankfort, Ill., and Earl Edward East (apprentice pharmacist).**

CHARGE: Between 8–2–55 and 8–9–55, *Dexedrine Sulfate capsules* and *thyroid tablets* were each dispensed once without a prescription, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Barker to each of 5 counts of information and by East to 2 counts involving dispensing of *capsules containing a mixture of secobarbital sodium and amobarbital sodium.*

DISPOSITION: 12–22–55. Barker—$400 fine; East—$100 fine.

4968. (F. D. C. No. 38570. S. Nos. 31–667/8 M, 35–721/3 M.)

INFORMATION FILED: 2–14–56, N. Dist. Ill., against **DeKoven-Calumet Drugs, Inc., Chicago, Ill., and Max M. Zenner (manager and pharmacist for the corporation).**

CHARGE: Between 7–12–55 and 8–1–55, *dextro-amphetamine sulfate tablets* were dispensed twice and *penicillin G potassium tablets* were dispensed 3 times without a prescription.

PLEA: Nolo contendere by each defendant.

DISPOSITION: 4–13–56. Corporation—$500 fine, plus costs; Zenner—$500 fine.

4969. (F. D. C. No. 38572. S. Nos. 17–941/4 M.)

INFORMATION FILED: 2–1–56, N. Dist. Ill., against **Mirsky Drug Co. (a corporation), Chicago, Ill., Joseph Mirsky (secretary and apprentice pharmacist), and Karl K. Wallman (vice president and pharmacist).**

CHARGE: Between 7–13–55 and 8–9–55, *dextro-amphetamine sulfate tablets* (counts 1 and 2) and *Gantrisin tablets* (counts 3 and 4) were each dispensed twice without a prescription.

PLEA: Nolo contendere—by corporation to all counts of information, by Mirsky to counts 1, 2, and 3, and by Wallman to count 4.

DISPOSITION: 3–2–56. Corporation fined $125, plus costs; Mirsky, $225; and Wallman, $75.

4970. (F. D. C. No. 38556. S. Nos. 30–177 M, 30–237 M, 30–601 M, 30–609 M, 38–121 M.)

INFORMATION FILED: 12–19–55, E. Dist. Ill., against **Pen-Yu Drug, Inc., West Frankfort, Ill., and Victor M. Penrod (president) and Ralph J. Yucus (secretary-treasurer).**

CHARGE: Between 8–3–55 and 8–9–55, *Gantrisin tablets* and *thyroid tablets* were each dispensed twice and *dextro-amphetamine sulfate capsules* were dispensed once without a prescription.

PLEA: Guilty—by corporation to each of 5 counts of information, by Penrod to 3 counts, and by Yucus to 2 counts.

DISPOSITION: 12–22–55. Imposition of sentence against corporation suspended; each individual fined $200.

4971. F. D. C. No. 37869. S. Nos. 1–324/5 M, 1–522/5 M.)

INFORMATION FILED: 7–11–55, N. Dist. Fla., against **Crestview Apothecary, Inc., Crestview, Fla., and Perry L. Smith (president) and Alto Alexander Borland (pharmacist).**

CHARGE: Between 1–8–55 and 1–12–55, *Gantrisin tablets* were dispensed twice and *Metandren Linguets, Dexedrine Sulfate tablets,* and *pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty—by corporation and Smith to each of 5 counts of information and by Borland to count 5.

DISPOSITION: 11–7–55. Corporation fined $1,500; Smith and Borland given suspended sentences of 6 months and 3 months in prison, respectively, and each placed on probation for 5 years.

4972. (F. D. C. No. 38571. S. Nos. 5–191/2 M.)

INFORMATION FILED: 2–14–56, N. Dist. Ill., against **Virgil Roger Rutili (a pharmacist employed by Croydon Drugs), Chicago, Ill.**

CHARGE: Between 6–29–55 and 7–6–55, *Seconal Sodium capsules* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–1–56. $500 fine, plus costs.

4973. (F. D. C. No. 38523. S. Nos. 15–057 M, 15–382 M, 15–682 M, 21–198/9 M.)

INFORMATION FILED: 3–6–56, Dist. Kans., against **Stanley M. Meyers, t/a Meyers Professional Pharmacy, Topeka, Kans.**

CHARGE: Between 5–4–55 and 9–24–55, *Seconal Sodium capsules* were dispensed 5 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 3–21–56. $500 fine and probation for 2 years.

4974. (F. D. C. No. 38535. S. Nos. 13–546/50 M, 13–581 M.)

INFORMATION FILED: 11–22–55, E. Dist. Pa., against Ralph Shayne, t/a Shayne Pharmacy, Philadelphia, Pa.

CHARGE: Between 5–2–55 and 5–18–55, *Tuinal capsules* were dispensed twice and *thyroid tablets* were dispensed once without a prescription, and *Tuinal capsules* were dispensed twice and *Gantrisin tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 1–27–56. $900 fine and probation for 3 years.

4975. (F. D. C. No. 38562. S. Nos. 29–727 M, 29–735 M.)

INFORMATION FILED: 1–27–56, S. Dist. N. Y., against Kleb Drug Co., Inc., New York, N. Y., and Joseph Klebanoff (president).

CHARGE: Between 5–25–55 and 6–23–55, *Tuinal capsules* and *dextro-amphetamine sulfate tablets* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 3–14–56. $400 fine against defendants jointly.

4976. (F. D. C. No. 38554. S. Nos. 30–178 M, 30–238/9 M, 30–602 M, 30–612/13 M, 38–123 M.)

INFORMATION FILED: 12–19–55, E. Dist. Ill., against George N. Kimberlin, t/a Holland Drug Co., West Frankfort, Ill., and William Davis (apprentice pharmacist).

CHARGE: Between 8–3–55 and 8–11–55, *thyroid tablets* and *Dexedrine Sulfate capsules* were each dispensed twice and *Gantrisin tablets* and *Benzedrine Sulfate tablets* were each dispensed once without a prescription, and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty—by Kimberlin to each of 7 counts of information and by Davis to 5 counts.

DISPOSITION: 12–22–55. Kimberlin fined $400 and Davis $200.

4977. (F. D. C. No. 36675. S. Nos. 85–060/1 L, 85–067 L.)

INFORMATION FILED: 1–4–55, E. Dist. Pa., against Max L. Bliss, t/a Bliss Drug Store, Philadelphia, Pa.

CHARGE: Between 2–18–54 and 3–1–54, *thyroid tablets* were dispensed twice and *AM Plus capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 1–26–56. Defendant fined $1,500, given 1 year suspended prison sentence, and placed on probation for 3 years.

4978. (F. D. C. No. 38547. S. Nos. 4–771 M, 5–121 M, 5–735 M.)

INFORMATION FILED: 12–9–55, N. Dist. Ill., against Herbert R. Esh, t/a Esh Drug Store, Barrington, Ill.

CHARGE: Between 12–13–54 and 1–29–55, *Pentids tablets* were dispensed twice and *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 12–28–55. $400 fine, plus costs.

4979. (F. D. C. No. 38545. S. Nos. 4–777 M, 5–734 M, 5–737 M, 5–739 M.)

INFORMATION FILED: 11–29–55, N. Dist. Ill., against **Althafer's Drugstore (a partnership), Crystal Lake, Ill., and Richard W. Copeland (a partner in the partnership) and Gertrude M. H. Copeland (apprentice pharmacist).**

CHARGE: Between 12–10–54 and 2–5–55, *Pentids tablets* (counts 1, 2, and 3) were dispensed 3 times and *Pondets troches* (penicillin-bacitracin troches) (count 4) were dispensed once without a prescription.

PLEA: Nolo contendere—by partnership to each of 4 counts of information, by Richard W. Copeland to counts 1, 2, and 4, and by Gertrude M. H. Copeland to count 3.

DISPOSITION: 12–9–55. Partnership—$100 fine, plus costs; Richard W. Copeland—$200 fine; and Gertrude M. H. Copeland—$100 fine.

4980. (F. D. C. No. 38130. S. Nos. 4–952 M, 5–045/8 M.)

INFORMATION FILED: 8–4–55, N. Dist. Ill., against **Sidney Brown and Frank Davis (partners in, and pharmacists for, Brown's Pharmacy), Chicago, Ill., and Grant V. McCain (an employee).**

CHARGE: Between 1–7–55 and 1–18–55, *Pondets troches* and *Pentids tablets* were each dispensed twice and *Metandren Linguets* were dispensed once without a prescription.

PLEA: Nolo contendere—by McCain to dispensing *Pondets troches*, by Brown to dispensing *Pentids tablets*, and by Davis to dispensing *Pentids tablets* and *Metandren Linguets*.

DISPOSITION: 10–14–55. McCain fined $100; Davis, $200, plus costs; and Brown, $150.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1957

D. D. N. J., F. D. C. 4981–5000. Issued April 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4981–5000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings which were terminated with the entry of default decrees of condemnation. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 29, 1957.*

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*For drugs in violation of prescription labeling requirements, see Nos. 4983, 4986; presence of a habit-forming narcotic without warning statement, No. 4986; omission of, or unsatisfactory, ingredients statements, Nos. 4986, 4990; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 4986.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 4981–5000

Adulteration, Section 501 (a) (1), the article consisted in part of a filthy or decomposed substance; Section 501 (a) (2), the article had been held under insanitary conditions; Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (b) (1), the article was in package form, and it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling; Section 502 (l), the article purported to be and was represented as a drug composed partly of a kind of penicillin, chlortetracycline, or Chloromycetin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; Section 503 (b) (4), the article was subject to Section 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4981. Calcium gluconate. (F. D. C. No. 38639. S. No. 30–305 M.)

QUANTITY: 272 10-cc. ampuls at Chicago, Ill.

SHIPPED: 10–7–55, from Memphis, Tenn. (a return shipment).

LABEL IN PART: (Ampul) "A–50 10 cc. Calcium Gluconate U. S. P. 10% Solution W/V in ampul water no preservative Intramuscular and Intravenous * * * 954."

LIBELED: 10–17–55, N. Dist. Ill.

CHARGE: 502 (j)—the article, when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling of the article, when shipped, namely, "Usual Dose: Adults, intravenous or intra-

muscular. 1 Gram daily or on alternate days; for children, intravenous 0.02 to 0.5 Gram," was dangerous to health because of its pyrogenic effect.

DISPOSITION: 12–16–55. Default—destruction.

4982. **E-Z thumb guard.** (F. D. C. No. 38970. S. No. 27–203 M.)

QUANTITY: 11 display cards, each containing 6 *E-Z thumb guards*, at Phenix City, Ala.

SHIPPED: 12–5–55, from New York, N. Y., by E-Z Products Co.

ACCOMPANYING LABELING: (Display card and card attached to each thumb guard) "E-Z Thumb Guard."

RESULTS OF INVESTIGATION: The device consisted of a piece of metal measuring approximately 1¾ inches in length and 1⅛ inches in width, containing a double row of rectangular perforations and folded so as to form a cylinder and pliable enough to be pressed snugly around the thumb or finger of a baby. Attached to the cylinder was a string long enough to be looped between the fingers and tied around the wrist for securing the thumb guard in place.

LIBELED: 2–27–56, M. Dist. Ala.

CHARGE: 502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that it would prevent thumb or finger sucking; that it would protect the baby's health, teeth, gums, and facial features; that it would guard the baby's teeth; and that it would easily and effectively stop the habit of thumb sucking; and 502 (j)—the article, when used as a baby's thumb guard as suggested in the labeling, would be dangerous to health.

DISPOSITION: 4–2–56. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

4983. **Au-Bi-Ol.** (F. D. C. No. 38873. S. No. 29–944 M.)

QUANTITY: 104 10-cc. vials and 2 100-cc. vials at Brooklyn, N. Y.

SHIPPED: Sometime after 3–29–51, from Hamburg, Germany, by E. Tosse & Co.

LABEL IN PART: (Vial) "Au-Bi-Ol 'Tosse-Germany' 1 cc. contains 0.09 g Bisuthsubsalicylate and 0.005 g Aurothiosalicylate, suspended in vegetable oil * * * Intragluteal * * * E. Tosse & Co., Hamburg."

LIBELED: 12–27–55, E. Dist. N. Y.

CHARGE: 503 (b) (4)—the article, when shipped, was a drug subject to 503 (b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription"; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2–27–56. Default—destruction.

4984. **Dental hemostat.** (F. D. C. No. 38695. S. No. 22–472 M.)

QUANTITY: 1,386 ¼-oz. btls. at Chicago, Ill.

SHIPPED: 8–3–55, from Portland, Oreg., by Ruson Laboratories, Inc.

LABEL IN PART: (Btl.) "Orylstat For Topical Use Only * * * Active Ingredients: Racemic Epinephrine (dimethylaminoethanolcatechol Hydrochloride) 8%, with chlorobutanol, a chloroform derivative, as a preservative 0.5%, N-(caprylcolaminoformylmethyl)-Pyridinium Chloride* 1:2000. Inert Ingredients: Distilled water, sodium chloride, 90% *Ruson Chloride."

RESULTS OF INVESTIGATION: Analysis showed that the article contained no N-(caprylcolaminoformylmethyl)-Pyridinium Chloride.

LIBELED: 11–17–55, N. Dist. Ill.

CHARGE: 502 (a)—the label statement "Active Ingredients * * * N-(caprylcolaminoformylmethyl)-Pyridinium Chloride* 1:2000" was false and misleading; and 505 (a)—the article, when shipped, was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2–8–56. Default—destruction.

4985. B & H inhalant powder. (F. D. C. No. 38747. S. No. 25–796 M.)

QUANTITY: 8 display placards, 21 vials each, and 2 cartons, 3 vials each, at Minneapolis, Minn.

SHIPPED: 5–23–55, from Billings, Mont., by B & H Laboratories.

LABEL IN PART: (Vial) "B & H Inhalant Powder Contains borate soda, silver nitrate, menthol."

ACCOMPANYING LABELING: Cards designated "Colds Asthma Hay Fever Headaches Sinus B & H Inhalant Powder 'Amazing Discovery'" and leaflets entitled "Sinus And Hay Fever Sufferers B & H Inhalant Powder."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 98.1 percent borax, 1.86 percent silver nitrate, and a small amount of menthol.

LIBELED: 12–16–55, Dist. Minn

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for colds, asthma, hay fever, and all kinds of headaches and sinus trouble; and 505 (a)—the article was a new drug which could not lawfully be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 2–3–56. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUGS FOR HUMAN USE

4986. Various drugs. (F. D. C. No. 38907. S. Nos. 37–041/2 M, 37–045 M 37–048 M, 37–056/9 M, 37–061 M, 37–063 M, 37–067/9 M, 37–073/83 M 37–085 M, 37–087/8 M.)

QUANTITY: 2 btls. containing a total of 1,650 *Roncovite tablets;* 4 btls. containing a total of 5,000 *Zilatone tablets;* 3 btls. and 1 drum containing a total of 28,000 *Creamalin tablets;* 1 btl. containing 800 *Pheno-Bepadol tablets;* 9 100-capsule btls. of *Fer-Dona capsules;* 2 btls. containing a total of 1,000 *Kiophyllin tablets;* 2 btls. containing a total of 650 *Pavatrine tablets;* 2 btls. containing a total of 4,000 *Amodrine tablets;* 1 1,100-capsule btl. of *Sulphocol capsules;* 6 btls. of *Hemosule capsules;* 2 btls. containing a total of 1,360 *Butisol Sodium capsules* (*Mol-Iron tablets*); 1 1,100-capsule btl., of *Propadrine capsules,* 92 vials of *Dibenzylethylenediamine dipenicillin G oral suspension;* 2 btls. containing a total of 200 *Bicillin-Sulfas tablets;* 1 btl. containing 109 *Sulfabiotic tablets;* 1 btl. of *Pansulfa with penicillin tablets;* 1 btl. of *Aureomycin Spersoids;* 8 envelopes containing a total of 700 *Diamox tablets;* 2 btls. of *Erythrocin;* 3 btls. of *Thorazine;* 3 boxes of *Aureomycin capsules;* 2 btls.

containing a total of 530 *Cortril tablets;* 5 60-cc. btls. of *pediatric Chloromycetin Palmitate;* 9 btls. of *penicillin Solvets;* 34 1-oz. btls. of *Paredrine-Sulfathiazole Suspension;* 2 btls. containing a total of 1,800 *Ventrex Kapseals;* and 4,200 *AM Plus capsules* in btls. and cartons, at Newark, N. J.

SHIPPED: On unknown dates, from Chicago, Ill., Indianapolis, Ind., Detroit, Mich., Cincinnati, Ohio, Philadelphia, Pa., and Brooklyn, Buffalo, and New York, N. Y.

LIBELED: 1–13–56, Dist. N. J.

CHARGE: 501 (c)—(*Pheno-Bepadol tablets*) the strength of the article differed from that which it purported and was represented to possess, namely, vitamin B_1 (thiamine) 3 milligrams; (*Fer-Dona capsules*) the vitamin B_1 content of the article fell below the labeled potency in vitamin B_1; (*Hemosule capsules*) the vitamin B_1 and C content of the article fell below the professed potency in vitamin B_1 and C; (*Ventrex Kapseals*) the vitamin B_1 content of the article fell below the professed potency in vitamin B_1; and (*AM Plus capsules*) the dextro-amphetamine sulfate, thiamine hydrochloride, and ascorbic acid content of the article fell below the professed potency in these substances.

502 (a)—(*Pheno-Bepadol tablets*) the label statement "Each Tablet contains: * * * vitamin B–1 (Thiamine) 3 milligrams" was false and misleading as applied to a product containing less than the declared amount of vitamin B_1 per tablet; (*Fer-Dona capsules*) the label statement "Six Capsules * * * Contains: * * * Vitamin B–1 2 mg." was false and misleading as applied to a product which contained not more than 1.5 milligrams of vitamin B_1 per 6 capsules; (*Hemosule capsules*) the label statement "Each Capsule Contains: * * * Thiamine HCl (Vitamin B_1) 1.0 mg. * * * Ascorbic Acid (Vitamin C) 15.0 mg." was false and misleading as applied to a product which contained 0.74 milligram of vitamin B_1 and 10 milligrams of vitamin C per capsule; (*Mol-Iron tablets*) the label statement "Each Tablet Contains: Ferrous Sulfate (3 gr.) 195 mg. Molybdenum Oxide (1/20 gr.) 3 mg." was false and misleading as applied to a product which contained no ferrous sulfate or molybdenum oxide; (*Ventrex Kapseals*) the label statement "Each Kapseal Represents: * * * Vitamin B_1 (Thiamine HCl.) 0.5 mg." was false and misleading as applied to a product which contained 0.22 milligram of vitamin B_1, per Kapseal; and (*AM Plus capsules*) the label statement "Each Capsule Contains Dextro-Amphetamine Sulfate 5 mg. * * * Thiamine Hydrochloride 2 mg. * * * Ascorbic Acid 37.5 mg." was false and misleading as applied to a product which contained no dextro-amphetamine sulfate, 1.3 milligrams of thiamine hydrochloride, and not more than 30 milligrams of ascorbic acid per capsule.

502 (b) (1)—(*Roncovite tablets, Creamalin tablets, Kiophyllin tablets, Pavatrine tablets, Amodrine tablets, Propadrine capsules, Bicillin-Sulfas tablets, Diamox tablets, Erythrocin, Thorazine,* and *Cortril tablets*) the labels failed to bear the names and places of business of the manufacturers, packers, or distributors.

502 (d)—(*Pavatrine tablets, Amodrine tablets,* and *Butisol Sodium capsules* [*Mol-Iron tablets*]) the articles contained a derivative of barbituric acid, and their labels failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

502 (e) (2)—(*Roncovite tablets, Zilatone tablets, Creamalin tablets, Kiophyllin tablets, Pavatrine tablets, Amodrine tablets,* and *Diamox tablets*) the labels failed to bear the common or usual name of each active ingredient.

502 (f) (1)—(*Roncovite tablets, Zilatone tablets, Creamalin tablets, Kiophyllin tablets, Pavatrine tablets, Sulphocol capsules, Mol-Iron tablets, Propadrine capsules, Diamox tablets,* and *Paredrine-Sulfathiazole Suspension*) the labeling failed to bear adequate directions for use.

502 (f) (2)—(*Propadrine capsules*) the labeling failed to bear adequate warnings to prevent misuse.

502 (l)—(*dibenzylethylenediamine dipenicillin G oral suspension, penicillin Solvets, Bicillin-Sulfas tablets, Sulfabiotic tablets,* and *Pansulfa with penicillin tablets*) the articles were represented as drugs composed in part of penicillin, and they were not from batches with respect to which certificates issued pursuant to law were effective; (*Aureomycin Spersoids* and *Aureomycin capsules*) the articles were represented as drugs composed in part of chlortetracycline, and they were not from batches with respect to which certificates issued pursuant to law were effective; and (*pediatric Chloromycetin Palmitate*) the article was represented as a drug composed in part of Chloromycetin, and it was not from a batch with respect to which a certificate issued pursuant to law was effective.

503 (b) (4)—(*Butisol Sodium capsules* [*Mol-Iron tablets*], *Bicillin-Sulfas tablets, Diamox tablets, Erythrocin, Thorazine, Cortril tablets,* and *Paredrine-Sulfathiazole Suspension*) the articles were drugs subject to 503 (b) (1), and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

All articles were adulterated and/or misbranded while held for sale.

The libel alleged also that 12 other products were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 2–14–56. Default—destruction.

DRUGS FOR VETERINARY USE

4987. Birdie-Tabs. (F. D. C. No. 38420. S. No. 26–804 M.)

QUANTITY: 25 boxes, 12 6-tablet vials each, at New Orleans, La.

SHIPPED: 7–28–55 and 8–11–55, from Dallas, Tex., by Birdie-Cure Co.

ACCOMPANYING LABELING: (Display card) "Aureomycin Chlortetracycline Birdie-Tabs for Canaries and Parakeets * * * Each 5 gr. tablet contains Aureomycin Chlortetracycline Veterinarian Soluble – 5 mg., Vit. B–12—0.1 mcg., Lactose, starch and kaolin" and circular entitled "Birdie-Gram."

LIBELED: 8–31–55, E. Dist. La.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective for stimulating appetite, resisting infection, protecting against disease, overcoming conditions that cause puffed-up feathers, lack of pep, sneezing, coughing, nasal discharge, watery eyes, loose droppings (diarrhea), gasping breath, and other symptoms of ill health in birds; and 502 (l)—the article was composed partly of chlortetracycline, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: 4–17–56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4988. Aqueous extract of pituitary anterior and ovarian. (F. D. C. No. 37547. S. Nos. 5–695/6 M.)

QUANTITY: 82 cartons, 25 2-cc. ampuls each, and 362 30-cc. vials at Evanston, Ill.

SHIPPED: Between 10–15–54 and 12–10–54, from Rensselaer, N. Y., by Winthrop-Stearns, Inc.

LABEL IN PART: (Ampul) "2 cc size Sterile Aqueous extract of Pituitary Anterior and Ovarian With procaine hydrochloride 1% and chlorobutanol"; (vial) "Multidose Vials – Sterile Aqueous extract of Pituitary Anterior – Ovarian * * * Each cc contains water soluble extractives from 5 gr. of Anterior Pituitary and 20 gr. of Ovarian Tissue with procaine HCl 1% in isotonic salt solution with chlorobutanol – George A. Breon and Company, New York 18, NY."

ACCOMPANYING LABELING: Leaflets entitled "[For Physicians' Information] The Administration of Aqueous Anterior Ovarian Substances."

LIBELED: 1–10–55; amended 7–20–55, N. Dist. Ill.

CHARGE: 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for menopausal nervous instability, essential amenorrhea, and dysmenorrhea; and 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: George A. Breon & Co., claimant, New York, N. Y., filed answers to the libel and to the amended libel, denying that the product was misbranded as alleged. On 8–11–55, interrogatories were served upon the claimant by the Government. The claimant withdrew its answer; and, on 10–5–55, the court entered a default decree of condemnation and destruction.

4989. Alberty products. (F. D. C. No. 36439. S. Nos. 83–633/7 L, 83–639/41 L.)

QUANTITY: 14 12-oz. btls., of *Alberty Phar-Oil*, 13 180-tablet pkgs. of *Alberty Special Formula tablets*, 9 200-tablet btls. and 57 475-tablet btls. of *Alberty Phloxo B tablets*, 6 200-pellet btls. and 21 475-pellet btls. of *Alberty's Lebara No. 2 pellets*, 29 3-lb cans and 54 12-oz. cans of *Instant Alberty Food*, 8 124-tablet btls. and 4 275-tablet btls. of *Ri-Co tablets*, 15 50-perle btls. and 3 350-perle btls. of *Alberty Garlic and Vegetable Oil Perles*, and 1 225-pellet btl. and 4 500-pellet btls. of *Alberty's Sabinol pellets* at Des Moines, Iowa.

SHIPPED: Between 7–2–53 and 1–25–54, from Hollywood, Calif., by Alberty Food Products.

LABEL IN PART: (Btl.) "Alberty Phar-Oil * * * A Dietary Food Supplement Ingredients: Cod Liver Oil, Wheat Germ Oil, Linseed Oil."

(Pkg.) "Alberty New Improved Special Formula Tablets A Dietary Supplement Ingredients: Kelp, DiCalcium Phosphate, Iron (ferrous) Gluconate, Copper Peptonate, Mixed Tocopheral Concentrate, Manganese Sulfate, Pantothenol, Para-Aminobenzoic Acid. In a base of Yeast, Liver Extract, Orchic

*See also No. 4986.

Substance, Nucleinic Acid, Spleen Substance, Pancreatin, and Excipients * * * Net Contents 180 App. 12-Grain Tablets."

(Btl.) "Alberty Phloxo B Tablets Vitamin B_1 with Homeopathic Amounts of Five Phosphates. Each Tablet Contains 40 Int. Units of Vitamin B_1 1/1000 gr. each of Phosphates of Iron, Potassium, Sodium, Calcium and Magnesium"; "Alberty's Lebara No. 2 Pellets Homeopathic Principle Each Pellet Contains: Celandine, Fringe-tree Barberry, Cinchona Off."

(Can) "Instant Alberty Food Special Dietary Food Made with Regular Alberty Food and Milk Made with Dried Whole and Skim Milk and a Special Grind of Cereal (Wheat, Barley) and Dibasic Calcium Phosphate."

(Btl.) "Ri-Co Tablets Homeopathic Combination * * * Each Tablet Contains: Lithium Benzoicum 3X Ammonium Phos. 3X Lycopodium 6X"; "Alberty Garlic and Vegetable Oil Perles * * * 6 Min. Perles Fresh Garlic Concentrated 8 to one And Combined in Vegetable Oil (No established therapeutic or nutritional value.) * * * a Convenient Way of Including Garlic Oil in the Diet"; "Alberty's Sabinol Homeopathic * * * Each Pellet Contains: Berberis Vulgaris 1X Lycopodium 3X Uranium Nit 6X Equisetum 3X."

LIBELED: 3–11–54, S. Dist. Iowa; libel amended 8–9–54.

CHARGE: 502 (f) (1)—while held for sale, the labeling of the above-mentioned articles failed to bear adequate directions for use for the purposes and conditions for which they were intended, namely, the following purposes and conditions for which the articles were offered orally by Mr. and Mrs. Kenneth Hackworth on 2–5–54, 2–9–54, and 2–11–54: *Alberty Phar-Oil*—in the treatment of nervousness, irritableness, menopausal distress, thyroid trouble, kidney disturbances, anemia, paralysis, muscular atrophy, coronary thrombosis, hypertensive heart disorders, rheumatic heart, Parkinson's disease, painful menstruation, cerebral palsy, multiple sclerosis, sterility, loss of sex interests, skin eruptions, burns, brittle nails, nephritis, catarrh, diseases of women, leg pains, bursitis, impaired functioning of the sex glands, prostate trouble, swelling of the prostate, and lack of libido and potency in men; *Alberty Special Formula tablets*—in improving libido and sexual strength, providing sex drive, increasing muscular and sexual activity, improving general health, providing better circulation and functioning of the blood making organs, and providing increased sexual desire; *Alberty Phloxo B tablets*—in providing good health and normal sex power and in treating hypertension and menopausal difficulties; *Alberty's Lebara No. 2 pellets*—in treating menopausal distress and nervousness and in restoring sex desire; *Instant Alberty Food*—in the treatment of rheumatism, arthritis, lumbago, and bursitis, and in restoring sexual vigor; *Ri-Co tablets*—in the treatment of sciatica, lumbago, and bursitis; *Alberty Garlic and Vegetable Oil Perles*—in the treatment of infertility, impotency, skin infections, colds, and influenza; and *Alberty's Sabinol pellets*—in the treatment of kidney sores, bladder sores, and pus in the kidneys.

502 (a)—when shipped, the label of *Alberty Phloxo B tablets*, *Alberty's Lebara No. 2 pellets*, *Ri-Co tablets*, and *Alberty's Sabinol pellets* contained the following false and misleading representations: that *Alberty Phloxo B tablets* were an adequate and effective treatment for sleeplessness, insomnia, irritability, and nervousness; that *Alberty's Lebara No. 2 pellets* were an adequate and effective treatment for liver conditions; that *Ri-Co tablets* were an adequate and effective treatment for pain and stiffness due to arthritis and rheumatism; and that *Alberty's Sabinol pellets* were an adequate and effective treatment for symptoms due to gravel or stone in the kidney and spasms of the ureters.

DISPOSITION: Alberty Food Products, claimant, filed an answer to the libel on or about 6–25–54, together with a set of interrogatories to be answered by the Government. Thereafter, the Government filed objections to the interrogatories and submitted a request for admissions. The claimant failed to reply to the request for admissions and to file any brief or argument to the objections to the interrogatories.

On 6–30–55, an application for default judgment was filed by the Government, and an order was entered setting the matter down for hearing. The claimant failed to appear at the hearing, and on 7–13–55, the court entered a decree condemning the goods and ordering their destruction.

4990. Various drugs. (F. D. C. No. 38189. S. Nos. 18–390/6 M, 18–398 M.)

QUANTITY: 135 1¼-oz. cartoned tubes of *Petty's pile ointment*, 21 1¼-oz. cartoned tubes of *Petty's analgesic balm*, 42 1¼-oz. cartoned tubes of *Petty's Heal-Aid ointment*, 59 1-oz. cartoned tubes of *Petty's In-A-Min-It*, 8 10-lb. bags and 8 3-lb. bags of *Petty's bathing salt*, 20 8-oz. jars of *Petty's Aroseptic Pulvis Antisepticus*, 50 ⅛-oz. cartoned vials of *Petty's toothache drops*, and 345 ⅔-oz. cartoned tubes of *Petty's zinc ointment*.

SHIPPED: Between 3–22–55 and 5–3–55, from Freeport, N. Y., by Pharmak, Inc.

LABEL IN PART: (Carton) "Petty's Pile Ointment * * * Contains Tannic Acid, Zinc Oxide, Boric Acid, Benzocaine, Cresol, Oils of Lavender, Thyme, Camphor and Eucalyptus"; "Petty's Analgesic Balm Counter-Irritant and Local Anesthetic * * * Contains Menthol, Methyl Salicylate, Lanolin."

(Tube) "Petty's Heal-Aid Ointment Antiseptic, Astringent, Soothing * * * Contains Calamine, Phenol, Oils of Sassafras and Eucalyptus, Ichthammol, Benzocaine"; "In-A-Min-It * * * Active Ingredients: Tragacanth U. S. P. Glycerin U. S. P. * * * Petty's."

(Bag) "Petty's Bathing Salt."

(Jar) "Petty's * * * Aroseptic Pulvis Antisepticus N. F."

(Vial) "Petty's Toothache Drops Alcohol 52% Chloroform 2% Oil Of Cloves Cinnamon Creosote Phenol Benzocaine."

(Tube) "Petty's Zinc Ointment Zinc Oxide Ointment."

LIBELED: 6–22–55, Dist. N. J.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained false and misleading representations that *Petty's pile ointment* was an adequate and effective treatment for blind, bleeding, and itching piles, both internal and external or protruding; that *Petty's analgesic balm* was an adequate and effective treatment for neuralgia, chilblains, sore throat, stiff muscles and joints, earache, pleurisy, sprains, bruises, and colds on the chest; that *Petty's Heal-Aid ointment* was an adequate and effective treatment for corns, bunions, callouses, chilblains, warts, bruises, boils, earache, piles, rectal irritations, eczema, and all burning or itching skin affections; that *Petty's In-A-Min-It* was effective in the prevention of appendicitis, convulsions in infants, and headaches; that *Petty's bathing salt* was an adequate and effective treatment for weak and impaired circulation; that *Petty's Aroseptic Pulvis Antisepticus* was an adequate and effective treatment for all types of wounds, sores, ulcers, burns, scalds, eczema, itching, skin eruptions, piles, foot itch, corns, and callouses; and that *Petty's zinc ointment* was an adequate and effective treatment for skin eruptions, sore nipples, weeping sores, and drying up excessive nasal secretions during colds in the head. 502 (e) (2)—the label of *Petty's*

Aroseptic Pulvis Antisepticus failed to bear the common or usual name of each active ingredient; 502 (f) (1)—the labeling of the *Aroseptic* failed to bear adequate directions for use as a douche, and the labeling of *Petty's toothache drops* bore no directions for use; 502 (f) (2)—the labeling of *Petty's pile ointment, Petty's Heal-Aid ointment,* and *Petty's Aroseptic Pulvis Antisepticus* failed to bear adequate warnings against use in bleeding piles, and the labeling of *Petty's toothache drops* failed to warn that the article was only for temporary use until a dentist could be consulted.

DISPOSITION: 8–2–55. Default—destruction.

DRUG AND DEVICE ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

4991. Dried stillingia root. (F. D. C. No. 39120. S. No. 2–128 M.)

QUANTITY: 14 50-lb bags at Marion, Va., in possession of R. T. Greer & Co.

SHIPPED: Between 4–12–55 and 7–12–55, from Fort Myers, Fla.

LIBELED: 4–30–56, W. Dist. Va.

CHARGE: 501 (a) (1)—contained rodent hairs and rodent urine; and 501 (a) (2)—held under insanitary conditions.

DISPOSITION: 6–14–56. Default—destruction.

4992. Rubber prophylactics. (F. D. C. No. 38713. S. No. 40–504 M.)

QUANTITY: 1,008 *rubber prophylactics* at St. Paul, Minn.

SHIPPED: 8–4–55 and 9–7–55, from North Kansas City, Mo., by Dean Rubber Mfg. Co.

LABEL IN PART: (Carton containing 3 prophylactics) "Peacocks Redi-Wet Rubbers In Foil * * * Hygienically Lubricated * * * These Redi-Wet Peacock Rubbers are hygienically Pre-Lubricated with proven exclusive formula."

RESULTS OF INVESTIGATION: Examination showed that the article consisted of rolled rubber prophylactics packaged individually in hermetically sealed metal foil containers. Each *rubber prophylactic* was moistened with a small amount of viscous liquid, intended to act as a lubricant during coitus. This liquid coating on the individual prophylactics was contaminated with an extensive and obvious mold growth.

LIBELED: 11–23–55, Dist. Minn.

CHARGE: 501 (a) (1)—contained, when shipped, a decomposed substance by reason of contamination with mold; 501 (c)—the purity and quality of the article fell below that which it purported and was represented to possess since the lubricant liquid used to coat the individual *rubber prophylactics* was contaminated with an extensive mold growth; and 502 (a)—the label statement "Hygienically Lubricated" was false and misleading as applied to a product contaminated with extensive mold growth.

DISPOSITION: 1–5–56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

4993. Elixir of terpin hydrate and codeine (2 seizure actions). (F. D. C. No. 38651. S. Nos. 23–837 M, 23–851 M.)

QUANTITY: 240 2-oz. btls. at Phoenix, Ariz.

*See also Nos. 4986, 4992.

SHIPPED: 2–2–55 and 9–1–55, from Los Angeles, Calif., by Rabin Co.

LABEL IN PART: (Btl.) "Gray Cross * * * Elixir of Terpin Hydrate and Codeine, N. F."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 67 percent of the declared amount of codeine.

LIBELED: 10–28–55 and 11–8–55, Dist. Ariz.

CHARGE: 501 (b)—the article, when shipped, purported to be and was represented as a drug, "Elixir of Terpin Hydrate and Codeine," the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium; and 502 (a)—the label statement "Each fluid ounce contains Codeine * * * 0.9 gr." was false and misleading.

DISPOSITION: 12–22–55. Default—destruction.

4994. Amphetoplex tablets. (F. D. C. No. 38645. S. No. 32–023 M.)

QUANTITY: 1 drum containing 50,000 tablets at Philadelphia, Pa., in possession of Continental Medical Supply Co.

SHIPPED: 7–7–55, from Camden, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 70 percent of the declared amount of vitamin B_1 (thiamine HCl).

LIBELED: 10–18–55, E. Dist. Pa.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1.5 milligrams of vitamin B_1 per tablet; and 502 (a)—the statement appearing in the labeling of the article "Each tablet contains: Thiamine HCl . . . 1.5 mgm." was false and misleading.

DISPOSITION: 12–14–55. Default—destruction.

4995. Vitamin B complex with vitamin B_{12}. (F. D. C. No. 38667. S. No. 32–124 M.)

QUANTITY: 101 10-cc. vials at Camden, N. J.

SHIPPED: On 9–27–54, the article was shipped from Newark, N. J., to the consignee, who was doing business in Philadelphia, Pa. The consignee subsequently moved and transported the article to its place of business in Camden, N. J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 25 percent of the declared amount of vitamin B_{12}.

LIBELED: On or about 11–7–55, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 15 micrograms of vitamin B_{12} per cubic centimeter; and 502 (a)—the label statement "Each cc. Contains * * * Vitamin B–12 . . . 15 mcg." was false and misleading.

DISPOSITION: 12–6–55. Default—the words "with Vitamin B–12" and "Vitamin B–12 . . . 15 mcg." were stricken from the labeling, and the article was delivered to a charitable institution.

4996. Liver–iron folic acid. (F. D. C. No. 38680. S. No. 32–122 M.)

QUANTITY: 53 25-cc. vials at Camden, N. J.

SHIPPED: 6–1–55, from Philadelphia, Pa.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 50 percent of the declared amount of folic acid.

LIBELED: On or about 11–14–55, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 2 milligrams of folic acid per 2 cc.; and 502 (a)—the label statement "Each 2 cc. contains: * * * Folic Acid 2 mg." was false and misleading.

DISPOSITION: 12–16–55. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4997. Ionic calcium. (F. D. C. No. 37982. S. No. 15–024 M.)

QUANTITY: 8 cases, 12 1-pt. btls. each, 12 cases, 12 1-qt. btls. each, and 2 cases, 4 1-gal. btls. each, at San Francisco, Calif.

SHIPPED: 4–7–55, from Eugene, Oreg., by Ionic Calcium Products Co.

LABEL IN PART: (Btl.) "IC No. 39 Ionic Calcium A liquid calcium supplement providing ionized calcium in natural alkaline solution for rapid absorption. Three tablespoons (1½ fluid oz.) provide not less than the following amounts: Calcium (in hypothetical comb.) 1.020 milligrams (with Cl_2 and CO_2) Caesium—120 p. p. m. Biochemic Tissue Salts: Potassium Chloride (KCl)—340 milligrams Sodium Chloride (NaCl)—115 milligrams Silica (SiO_2)—8 p. p. m. Trace Elements: Copper, Cobalt, Magnesium, Nickel and Iodine. No Alcoholic Content Added Certified Color pH 8–10."

ACCOMPANYING LABELING: Yellow card designated "I Am Desperately In Need Of Calcium" and leaflets designated "Synopsis Of Ionic Calcium Therapy Using IC No. 39."

RESULTS OF INVESTIGATION: The consignee affixed the labels described above to each bottle of the article after shipment. The above-mentioned yellow card and leaflets were sent to the consignee by the shipper.

LIBELED: 6–3–55, N. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for catarrhal and asthmatic troubles, allergy, toxemia, muscle soreness from exercise, Charley horse, anorexia, dyspepsia, arthritis, conjunctivitis, myopia, general nervousness, irritability, impatience, frequent pessimism, tendency toward unsociability, poor memory, labored thinking or concentration, slow healing of wounds, excessive scar formation, slow coagulation of blood, anemia, torpid liver, malnutrition in spite of adequate food intake, stretching of elastic fibers, varicose veins, hemorrhoids, visceroptosis, neurasthenia, constipation, poor oxidation, irregular heartbeat, tooth decay, brittle bones, gas, bloat, indigestion, general debility, premature senility, low vitality, lack of courage, distrustful attitude, lack of will power, and senility.

DISPOSITION: 11–2–55. Default—destruction.

4998. Verdazyme. (F. D. C. No. 38199. S. No. 20–618 M.)

QUANTITY: 20 btls. at Wichita, Kans.

*See also Nos. 4982, 4984–4990, 4992–4996.

SHIPPED: 4–15–55, from Kansas City, Mo., by E. H. Pratt (Verdazyme Laboratories).

LABEL IN PART: (Btl.) "Contents: 280 C. T., 6 Grains Verdazyme A concentrated natural extract of selected green cereal and other plants. Specially processed at low temperature, under vacuum, to retain maximum vitamin, mineral, enzyme, amino acid and chlorophyll values."

ACCOMPANYING LABELING: A circular entitled "Memo to Physicians: From: E. H. Pratt, founder * * * This is a preview of Verdazyme food tablets."

LIBELED: 6–24–55, Dist. Kans.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations and suggestions that the article was an adequate and effective treatment for arthritis, constipation, colds, tiredness, heart trouble, anemia, nervousness, polio, pregnancy, skin disorders, impotence, brittle finger nails, asthma, hay fever, liver disorders, muscle stiffness and soreness, overweight, underweight, allergies, and poor assimilation of foods.

DISPOSITION: 11–16–55. Default—destruction.

4999. Insect-O-Lite vaporizer and Tricol (triethylene glycol). (F. D. C. No. 38407. S. No. 24–737 M.)

QUANTITY: 12 cartons, each containing 1 *Insect-O-Lite vaporizer* and 1 btl. of *Tricol*, and 143 btls. of *Tricol* at Seattle, Wash.

SHIPPED: 5–26–55, from Cincinnati, Ohio, by Insect-O-Lite Co., Inc.

LABEL IN PART: (Device) "Insectolite"; (btl.) "Tricol * * * Air treatment grade Active Ingredient Triethylene Glycol 100% for use in Insect-O-Lite Vaporizer To aid in the reduction of air-borne bacteria and viruses * * * Contents 4 Fl. Oz."

ACCOMPANYING LABELING: Leaflets entitled "Insect-O-Lite * * * Vaporizer With Tricol."

RESULTS OF INVESTIGATION: The device was an electrically operated lamp for vaporizing volatile substances. The drug was intended for use with the lamp.

LIBELED: 8–31–55, W. Dist. Wash.

CHARGE: 502 (a)—the labeling of the articles, when shipped, contained false and misleading representations that the articles provided an adequate and effective treatment for preventing colds, influenza, psittacosis, throat infections, pneumonia, catarrhal fever, measles, mumps, scarlet fever, rheumatic fever, tonsillitis, otitis media, chickenpox, sinusitis, and respiratory infections.

DISPOSITION: 11–28–55. Default—destruction.

5000. Electreat device. (F. D. C. No. 38697. S. No. 9–595 M.)

QUANTITY: 26 cartons, each containing 1 device, at Los Angeles, Calif., in possession of Reuben Lieberman and John Dorsey, t/a Nu-Life.

SHIPPED: 7–26–55, from Peoria, Ill.

ACCOMPANYING LABELING: Leaflets designated "Atomic-Nu-Life" and business cards inscribed in part "Are You Looking For the Fountain Of Youth Atomic Nu-Life."

RESULTS OF INVESTIGATION: The device was an elongated metallic cylinder housing an induction coil with a make-and-break current switch, operated by two flashlight batteries. The cylinder had a small roller attachment at one end. When in operation, the device would give off an interrupted-type

electrical current at a high voltage but of very low intensity. The above-mentioned leaflets and business cards were prepared by the consignee and were distributed to prospective customers.

LIBELED: 11–18–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the device would provide an adequate and effective treatment for nervousness and insomnia, for extending the life span, acting as a fountain of youth, enabling one to grow strong, overcoming congestion and constipation, forcing super strength into the cells of the body, serving as a short cut to exercise, "enliving," oxygenating, resuscitating, and strengthening the parts of the body, overcoming sickness, preventing degeneration and chronic ailments, and providing good blood circulation by improving the muscular action of the heart.

DISPOSITION: 12–19–55. Default—delivered to the Food and Drug Administration.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4981 TO 5000

PRODUCTS

[1] (4988, 4989) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (4988, 4989) Seizure contested.

U. S. GOVERNMENT PRINTING OFFICE: 1957

D. D. N. J., F. D. C. 5001–5040 Issued May 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5001–5040

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or summary judgment, and (2) criminal proceedings which were terminated upon pleas of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firm and individual* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 29, 1957.*

CONTENTS*

*For omission of, or unsatisfactory, ingredients statements, see No. 5032; sale under name of another drug, No. 5009; cosmetic, actionable under the drug provisions of the Act, No. 5033.

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SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5001–5040

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of the users; Section 502 (i) (3), the article was offered for sale under the name of another drug.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

5001. Rubrafolin capsules, Tocopherex capsules, Latrodol tablets, and Prantal methylsulfate tablets. (F. D. C. No. 38943. S. No. 46–119 M.)

QUANTITY: 1 100-capsule btl. of *Rubrafolin capsules*, 1 100-capsule btl. of *Tocopherex capsules*, 1 100-tablet btl. of *Latrodol tablets*, and 1 100-tablet btl. of *Prantal methylsulfate tablets* at Upper Darby, Pa., in possession of Post Cut Rate Store.

SHIPPED: The articles were shipped in interstate commerce by persons unknown at unknown times.

LABEL IN PART: (Btl.) "Rubrafolin * * * Vitamin B12 Concentrate and Folic Acid Caution: Federal law prohibits dispensing without prescription"; "Tocopherex * * * d, alpha tocopheryl acetate in oil 25 Int. Units Vitamin E Caution: Federal law prohibits dispensing without prescription"; "Latrodol * * * Caution: Federal law prohibits dispensing without prescription"; and "Prantal Methylsulfate Brand of Diphenmethanil Methylsulfate Caution: Federal law prohibits dispensing without prescription."

RESULTS OF INVESTIGATION: The drugs were not exempt from the requirement of bearing adequate directions for use in their labeling since the Post Cut Rate Store, which held possession of the drugs, was unlawfully engaged in dispensing prescription drugs. The store did not employ a registered pharmacist and was not under the management of one, and thus the sale of drugs at retail was contrary to the laws of Pennsylvania which require that retail sales of such drugs be made by or under the supervision of a registered pharmacist.

LIBELED: 2–9–56, E. Dist. Pa.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped and while held for sale, failed to bear adequate directions for use.

DISPOSITION: 3–8–56. Default—destruction.

5002. Powdr-X. (F. D. C. No. 38953. S. No. 26–434 M.)

QUANTITY: 100 cases, 12 6-oz. pkgs. each, at Minneapolis, Minn., in possession of L. M. Gray, t/a Powdr-X Co.

SHIPPED: During 1946, from Westcliffe, Colo.

LABEL IN PART: (Pkg.) "Powdr-X For Internal Use * * *An impalpable mineral powder consisting of complex silicates of sodium, potassium, calcium, magnesium, aluminum, iron, manganese, zinc, cobalt, nickel, vanadium and titanium, having approximately the following composition: SiO_2 70.00% MnO .39% Al_2O_3 12.54% ZnO .076% Fe_2O_3 2.39% CoO Trace CaO .87% NiO Trace MgO .78% TiO_2 Trace K_2O 4.99% V_2O_5 Trace Na_2O 2.73% Powdr-X Company 5025 Queen Avenue South Minneapolis 10, Minnesota."

LIBELED: 2–16–56, Dist. Minn.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for gastric ulcers and gastric intestinal distress; and 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of glaucoma, osteomyelitis, tuberculosis of the bone, gangrene, cancer, and cataracts, for which it was recommended orally by L. M. Gray.

DISPOSITION: 4–12–56. Default—destruction.

5003. Pastilla candy, Albert Christy's Big 3 Compound capsules, Mellanine capsules, and rubber exercisers. (F. D. C. No. 38729. S. Nos. 7–484/5 M, 7–487/8 M, 42–390 M, 42–394 M.)

QUANTITY: 15 ½-lb. boxes of *Pastilla candy*, 51 60-capsule boxes of *Albert Christy's Big 3 Compound capsules*, 47 100-capsule boxes of *Mellanine capsules*, and 56 unlabeled *rubber exercisers* at Denver, Colo., in possession of Albert Christy.

SHIPPED: The candy and devices were shipped from Hollywood, Calif., on an unknown date, and *Albert Christy's Big 3 Compound capsules* and *Mellanine capsules* were shipped from Detroit, Mich., on 9–29–55.

RESULTS OF INVESTIGATION: During the course of lectures by Albert Christy, representations were made concerning the efficacy of the above-mentioned articles for the conditions and purposes set forth below.

The device involved was a strip of rubber approximately 22 inches long and 2 inches wide.

LIBELED: 12–12–55, Dist. Colo.

CHARGE: 502 (f) (1)—the labeling of the articles, while held for sale, failed to bear adequate directions for use for the diseases, conditions, and purposes for which they were recommended orally by Albert Christy, namely, (Pastilla candy) to prevent piles, constipation, congestion, asthma, hay fever, and sinus trouble; (Albert Christy's Big 3 Compound capsules) to treat arthritis and to enable one to live longer; (Mellanine capsules) to treat arthritis, muscular atrophy, rheumatism, stiff and swollen joints, high blood pressure, low blood pressure, anemia, leukemia, cataract, glaucoma, hardening of the arteries, gallstones, and kidney stones; and (rubber exercisers) to prevent cancer of the breast and to treat varicose veins and bursitis.

DISPOSITION: 2–15–56. Default—destruction.

5004. Electrosonic ultrasonic therapy device. (F. D. C. No. 37309. S. No. 88–898 L.)

QUANTITY: 2 devices at Milwaukee, Wis.

SHIPPED: 2–2–54, from Albion, Mich., by Scientific Instrument Co.

LABEL IN PART: (Nameplate) "Ultrasonic The Scientific Instrument Company Albion, Michigan U. S. A. Caution To Be Used By Or On The Prescription Of A Physician Only."

ACCOMPANYING LABELING: 2 booklets entitled "Operating Instructions for Electrosonic Instrument," 16 reprints of an article from the Los Angeles Times entitled "Super-Sound Treatment Aids Arthritics, Hospital Says," 25 reprints of an article from Your Life Magazine of September 1952 entitled "Attacking Disease with Sound Waves," 14 reprints of an article from the May 1952 issue of The British Journal of Physical Medicine entitled "Prolapse of Intervertebral Discs Treated with Ultrasonic Waves," 24 reprints of an article from the February 18, 1952 issue of the New York Times entitled "Diseases Treated By Supersonic Aid," 23 reprints of an article from the June 1951 issue of The British Journal of Physical Medicine entitled "Diseases of the Spine Treated With Ultrasonic Waves," 2 reprints of an article from the May 1952 issue of Postgraduate Medicine entitled "The Myofascial Genesis of Pain," 2 leaflets entitled "Latest Reports and Lectures of Scientific Papers on Ultrasonic Therapy," and 3 leaflets entitled "Investigate the New Electrosonic Sound Wave Instrument."

RESULTS OF INVESTIGATION: According to its label and accompanying labeling, the device was intended for the production of ultrasonic energy for therapeutic use, but the operator was nowhere provided with information as to the frequency of the ultrasonic energy output and information as to the amount of ultrasonic energy given off by the device for the various settings of the output control mechanism. Since it was essential that the operator of the device be informed as to the frequency of the ultrasonic energy and the amount of ultrasonic energy output for the various settings of the output control mechanism, the labeling of the article did not bear information as to the use of the device as required by regulations.

LIBELED: 10–18–54, E. Dist. Wis.

CHARGE: 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: 12–1–55; amended 12–20–55. Default—delivered to Food and Drug Administration.

5005. Hemovitameter device. (F. D. C. No. 39023. S. No. 51–480 M.)

QUANTITY: 1 *Hemovitameter device* bearing a segmented dial on which the segments were labeled with such designations as "digestion, blood, tissue, cell life," etc., at Albuquerque, N. Mex., in possession of Dr. S. C. Wyatt, D. C.

SHIPPED: During 1954, from Eckley, Colo., by Hemovitameter Laboratories, Inc.

ACCOMPANYING LABELING: Leaflet reading, in part, "To: Hemovitameter Co. Denver, Colo. * * * Vitality Element 66–4–8 general poison 59–2–7 inflamation 67–2–6 tissue degeneration."

RESULTS OF INVESTIGATION: The consignee placed in local newspapers advertisements by which the device was offered for use in obtaining information concerning various conditions which a person might have.

In actual use the consignee would have the patient take hold of two bars or electrodes that emerged from the device, and "readings" were taken which,

by reference to the dial and to the above-mentioned leaflet, were claimed to enable the consignee to determine the patient's condition.

LIBELED: 4–11–56, Dist. N. Mex.

CHARGE: 502 (a)—the labeling of the device, when shipped and while held for sale, contained false and misleading representations that the device was effective for diagnosing impaired digestion, abnormal conditions of the blood and tissues, the state of the body's cell life, the condition of the body's temperature regulating mechanism, the condition of the hair, teeth, eyes, and nails, the status of the iron balance in tissue digestion, the condition of one's bones, muscular functions, thyroid gland, brain, nerves, blood cell development, a condition of retarded growth, skin conditions, the condition of one's circulation and muscle function, abnormal tissue respiration, whether or not one requires a blood builder, a condition of general poisoning, inflammation, tissue degeneration, conditions due to bacterial toxins, a poisoned condition of the bowels, hyperacidic condition of the blood, conditions associated with excessive uric acid in the system, catarrh, streptococcus infection, staphlococcus infection, cancer, tuberculosis, conditions caused by excessive pressure on the nerves, sarcoma, ulcers, the state of one's glandular activity, calculi, anemia, fibroids, goiter, infestation by intestinal parasites, cysts, tumors, conditions due to scar tissue formation, rheumatism, cholelithiasis, eczema, and a toxic condition caused by excessive amounts of aluminum in the body.

502 (f) (1)—the labeling of the device, when shipped and held for sale, failed to bear adequate directions for use for diagnosing the conditions appearing in its labeling, since the labeling bore no directions for diagnosing such conditions, and it is impossible to devise adequate directions for such purposes and conditions. The labeling of the device failed also to bear adequate directions for use for obtaining information concerning one's heart action, nerve energy, the nature of one's ailments, the causes of one's ailments, and one's mineral and vitamin deficiencies, which were the conditions for which the device was intended and for which it was offered in the newspaper advertisements while held for sale.

DISPOSITION: 5–11–56. Default—delivered to Food and Drug Administration.

DRUGS FOR VETERINARY USE

5006. S–M capsules. (F. D. C. No. 38425. S. No. 15–560 M.)

QUANTITY: 1,156 boxes at Stockton, Calif., in possession of the Stockton Veterinary Supply Co.

SHIPPED: At various times from New York, N. Y.

LABEL IN PART: (Box) "Dr. Saunders * * * S–M Capsules Sodium Sulfamethazine Highly Recommended for Treating Many Bacterial Infections Contents: 6 Capsules * * * Directions: For Cattle and Horses: One Capsule for each 500 pounds of body weight. If necessary repeat every 24 hours until better."

RESULTS OF INVESTIGATION: The article had been shipped in powder form in bulk drums labeled, in part, "Sulfamethazine"; and, after its receipt by the consignee, the article was encapsulated and repacked into boxes labeled as described above.

Analysis showed that the article was sulfamethazine and not sodium sulfamethazine as declared on the box label.

LIBELED: 9–15–55, N. Dist. Calif.

CHARGE: 501 (d) (2)—while held for sale, sulfamethazine had been substituted for sodium sulfamethazine, which the article was represented to be; 502 (a)—the label on the boxes of the article contained false and misleading representations that the article consisted of sulfamethazine and that it was an adequate and effective treatment for retained afterbirth, congested lungs, and acute mastitis in cattle, and distemper and colds in horses.

502 (f) (2)—the labeling of the article failed to warn that the article may cause severe toxic reactions and irreparable damage if the blood levels become too high; that constant supervision of the animals was essential during treatment; and that use of the article should be discontinued if toxic symptoms appeared.

DISPOSITION: 12–1–55. Consent—claimed by Stockton Veterinary Supply Co. and relabeled.

5007. Solu-Stilbestrol. (F. D. C. No. 38980. S. No. 26–201 M.)

QUANTITY: 23 1-gal. cans at Coon Rapids, Iowa.

SHIPPED: 12–28–54 and 4–1–55, from Chicago, Ill., by Vitamins, Inc.

LABEL IN PART: (Can) "Vit Inc 1 Gal. Solu-Stilbestrol-50 Containing 50 gm. diethylstilbestrol with a solubilizing agent dissolved in 1 gal. molasses. *CAUTION:* For manufacturing, processing or repackaging of the preparation of a new drug limited by federal law to investigational use. Control #15530 Manufactured by Vitamins, Inc. 809 W. 58th St. Chicago 21, Ill., U. S. A. For Manufacturing Use."

RESULTS OF INVESTIGATION: Diethylstilbestrol intended for feeding to cattle for increasing their weight is regarded as a "new drug" ingredient.

Vitamins, Inc., filed a new-drug application for the article on 6–10–55 and submitted data concerning the use made of the article by the consignee, Garst Co., Coon Rapids, Iowa. These data were verified by information obtained by Food and Drug inspectors and showed that Garst Co. mixed the diethylstilbestrol preparation with cattle feed and fed the resultant mixture to its animals for fattening purposes, and showed further that no scientific tests of any real nature were conducted in connection with the feeding. In such circumstances, the new-drug application was not made effective.

LIBELED: On or about 3–8–56, N. Dist. Iowa.

CHARGE: 502 (f) (1)—the label of the article, when shipped and while held for sale, did not bear adequate directions for use, and the article was not entitled to any exemption from that requirement since the article had not been used and was not being used only in the manufacture of a new drug limited to investigational use as provided in the regulations.

DISPOSITION: 4–24–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5008. Various drugs. (F. D. C. No. 37994. S. Nos. 19–261/71 M.)

QUANTITY: 161 btls. of *Asmax tablets*, 151 btls. of *Lipolin*, 108 btls. of *Aratex tablets*, 6 btls. of *amino acid wafers*, 35 btls. of *Rectone tablets*, 50 btls. of *herbal diuretic tablets*, 56 14-oz. btls. and 13 8-oz. btls. of *Detoxo*, and 54 btls. of *Glutamins tablets* at Akron, Ohio.

*See also No. 5006.

SHIPPED: Between 10–20–54 and 3–31–55, from Los Angeles, Calif., by Pacific Mineral Industries.

LABEL IN PART: (Btl.) "Pacific Mineral Industries P. M. I. * * * ASMAX An Organic Formula Containing Elocampane Root Yerba Santa Dragon Turnip Cubeb Berries Ipecac Root Horehound Herb White Pine Compound Irish Moss * * * 120 Tablets * * * A Dietary Supplement," "Lipolin A Dietary Supplement To aid in the utilization of fats and to aid in the prevention of fatty infiltration of the liver. * * * 80 Caplets Each 3 Caplets Contain Methionine 50 Mg. Inositol 50 Mg. Choline (Dihydrogen Citrate) 123 Mg. Rutin 5 Mg. Plus excipients added as filler and coloring," "Lipolin To aid in the Utilization of Fats and the Prevention of Fatty Infiltration of the Liver * * * 90 tablets Each 2 tablets contain: Methionine, 150 mg. Choline, 300 mg. Betaine, 150 mg. Inositol, 150 mg. Rutin, 20 mg. in a base of the wonder herb Serpentaria Root," "Aratex Calcium Phosphorus Thiamine Vitamin D Compounded with A Special Herbal Base * * * Gentian Root Black Cohosh Buckbean Leaves Bitter Root Genseng Root Cinchona Bark Colombo Root Tamarac Bark The above herbs are blended in special base of tablet 120 Tablets," "New Improved Protamins B_1 B_{12} B_2 in Amino Acid Wafers * * * 150 Wafers * * * 2 Wafers with each of three meals (6 wafers) daily will supply:—Vitamin B–1 6 Mg. * * * Vitamin B–2 6 Mg. Vitamin B–12 6 Mcg. * * * Plus 45 gr. of protein hydrolysate and 40 gr. of whey. The base material supplies the following essential and non-essential amino acids in varying amounts: Arginine Methionine Tyrosine Histidine Threonine Cystine Lysine Leucine Asparatic Acid Tryptophane Isoleucine Glutamic Acid Phenylalanine Valine," "Rectone * * * An adjuvant for the relief of symptoms of rectal discomfort and body tonic. * * * 120 Tablets Each tablet contains a pure blend of the following herbs in a molasses base: Poke Root Mandrake Root Violet Leaves Flax Seed Figwort Herbs Comfrey Root Culvers Root Mullein Leaves Myrrh Gum Foenugreek Seed White Oak Bark Lobelia Herb Golden Seal Root Pilewort Herb Cascara Sagrada Bark Slippery Elm Bark Witch Hazel Bark Cranesbill Root," "120 Tablets * * * Formula S. B. K. A Herbal Diuretic Gravel Root Queen of Meadow Herb Althea Root Wild Carrot Leaves Pichi Tops Uva Ursi Leaves Hydrangea Root Celery Seed Shave Grass Couch Grass Root With Oil of Juniper Berries Formulated and Distributed by Pacific Mineral Industries Hollywood, California," "S. B. K. A Herbal Diuretic Gravel Root Queen of Meadow Herb Althea Root Wild Carrot Leaves Pichi Tops Uva Ursi Leaves Hydrangea Root Celery Seed Shave Grass Couch Grass Root With Oil of Juniper Berries Distributed by Ralph Brennan 195 Melbourne Ave. Akron, Ohio * * * 120 Tablets," "Formula Detoxo To eliminate noxious toxins, putrefaction, and mucus from the gastro-intestinal tract. To increase Lactobacillus in the gastro-intestinal tract. Contents Acidophilus Lactobacillus (Placed in preparation) Blond Plantago Ovata Organic Pectin Magnesium Trisilicate Flavor Added," and "120 Glutamins A Food Supplement. Each 10 gn. sodium glutamate tablet contains 8.69 gns. Glutamic Acid, 1 mgm. Thiamine HCL–B_1 Excipients as binder and coloring added."

ACCOMPANYING LABELING: Leaflets entitled "Asthma And Allied Bronchial Conditions * * * Asmax," "Lipolin," "Arthritis Rheumatism Aratex," "Hemorrhoids * * * Rectone," "Kidney And Bladder Conditions * * * S. B. K. A Herbal Diuretic," "Detoxo," and "Doctor's Order Form."

LIBELED: 6–1–55, N. Dist. Ohio.

CHARGE: 501 (c)—When shipped, the strength of the *Detoxo* differed from, and its quality fell below, that which it purported and was represented to possess since its labeling represented that the article contained a significant number of viable *Lactobacillus acidophilus* micro-organisms when such was not the case; and 502 (a)—the labeling of the articles, when shipped, contained the following false and misleading representations:

(a) That the *Asmax tablets* was an adequate and effective treatment for asthma and allied bronchial conditions, affections of the throat and lungs due to phlegm accumulations in the air passages, spasms of the respiratory system, and conditions requiring respiratory stimulation;

(b) That the *Lipolin* was an adequate and effective treatment for prevention of fatty infiltration of the liver, high blood pressure, hardening of the arteries, liver conditions, capillary fragility, liver damage, cirrhosis of the liver, necrosis of the liver, infective hepatitis, diabetes, multiple sclerosis, alcoholism, psoriasis, gallbladder conditions, and affections of the spleen;

(c) That the *Aratex tablets* were an adequate and effective treatment for arthritis, rheumatism, impaired glandular function, overacid conditions of the body, weakened veins, impure blood, inflammation, fever, nausea, and bursitis;

(d) That the *amino acid wafers* were an adequate and effective treatment for gastrointestinal conditions;

(e) That the *Rectone tablets* were an adequate and effective treatment for piles, impaired glandular function, sluggish liver, inflammation, irritability, bleeding, impaired body functions, and spasms;

(f) That the *herbal diuretic tablets* were an adequate and effective treatment for kidney conditions, bladder conditions, gravel and sediment in the bladder, and pus in the urinary system;

(g) That the *Detoxo* was an adequate and effective treatment for toxemia and affections of the gastrointestinal tract;

(h) That the *Glutamins tablets* were an adequate and effective treatment for epilepsy, nerve exhaustion, melancholy, and mental slowness, and for providing regeneration of nerve tissue, mental uplift, and change in personality.

DISPOSITION: 7–21–55. Default—destruction.

5009. Rauwolfia serpentina. (F. D. C. No. 37558. S. No. 6–621 M.)

QUANTITY: 2 100-lb. drums and 1 37-lb. drum of "Pow. Rauwolfia Serpentina"; 5 drums containing 750,000 tablets, 22 btls., 1,000 tablets each, 7 btls., 500 tablets each, and 32 btls., 100 tablets each, of "Powdered Whole Root Rauwolfia Serpentina" 100-mg. size; and 7 btls., 5,000 tablets each, 16 btls., 1,000 tablets each, 17 btls., 500 tablets each, and 64 btls., 100 tablets each, of "Powdered Whole Root Rauwolfia Serpentina" 50-mg. size, at Cincinnati, Ohio.

SHIPPED: The powdered *Rauwolfia* was shipped in bulk drums on 9–13–54, from New York, N. Y., by Prentiss Drug and Chemical Co.

LABEL IN PART: (Powder) "Pow. Rauwolfia Serpentina"; (tablets) "Wolfina Brand of Powdered Whole Root Rauwolfia Serpentina."

RESULTS OF INVESTIGATION: Upon receipt of the shipment of powdered *Rauwolfia*, the consignee manufactured a portion into tablets. An examination showed that the article contained large amounts of the ground root of a species of *Rauwolfia* other than *Rauwolfia serpentina*.

LIBELED: 1–11–55, S. Dist. Ohio.

CHARGE: 501 (d) (2)—the article, when shipped, was represented as *Rauwolfia serpentina*, and a substance other than *Rauwolfia serpentina* had been substituted in whole or in part therefor; 502 (a)—the label designation "Rauwolfia Serpentina" was false and misleading; and 502 (i) (3)—the article was a drug which was not *Rauwolfia serpentina*, and it was offered for sale under the name of another drug, *Rauwolfia serpentina*.

DISPOSITION: 3–23–56. Default—destruction.

5010. Digitalis tablets. (F. D. C. No. 38974. S. No. 42–339 M.)

QUANTITY: 1 fiber drum of 11,425 tablets and 2 fiber drums, each containing 65,000 tablets, at Denver, Colo.

SHIPPED: 2–22–55, from New York, N. Y.

RESULTS OF INVESTIGATION: The tablets were manufactured by the consignee from powdered digitalis leaves, which had been shipped in bulk from New York, N. Y.

Analysis showed that the digitalis potency of the article was less than 85 percent of its declared potency of 1½ grains of U. S. P. digitalis per tablet. The United States Pharmacopeia provides that the potency of digitalis, calculated from the prescribed assay preparation, is satisfactory if the result is not less than 85 percent and not more than 120 percent of the labeled potency.

LIBELED: 3–7–56, Dist. Colo.; libel amended 3–15–56.

CHARGE: 501 (b)—the strength of the article while held for sale differed from the standard set forth in the United States Pharmacopeia for *digitalis tablets;* and 502 (a)—the label statement "Each Tablet Contains: Digitalis, U. S. P. ---- 1½ gr." was false and misleading as applied to an article which contained less than 1½ grains of U. S. P. digitalis per tablet.

DISPOSITION: 5–9–56. Default—destruction.

5011. Befolin No. 1. (F. D. C. No. 38732. S. No. 9–636 M.)

QUANTITY: 12 10–cc. vials at Los Angeles, Calif.

SHIPPED: During 1954, from St. Louis, Mo.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 33 percent of the declared amount of vitamin B_{12}.

LIBELED: 12–13–55, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each CC, Contains: Vitamin B–12 Activity From (Beef) Liver Injection U. S. P. Equivalent to Cyanocobalamin 5 Mcg." was false and misleading.

The libel alleged also that another product, Ferro-Calscorbate, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–19–56. Consent—destruction.

5012. Cepevit. (F. D. C. No. 38719. S. No. 9–597 M.)

QUANTITY: 501 30–cc. vials at Los Angeles, Calif.

SHIPPED: 6–30–54, from New York, N. Y.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 84 percent of the declared amount of vitamin C.

LIBELED: 12–8–55, S. Dist. Calif.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, 1,500 milligrams of sodium ascorbate equivalent to vitamin C; and 502 (a)—the label statement "Each Vial Contains: Sodium Ascorbate Equivalent To Vitamin C. . . . 1,500 mg." was false and misleading.

DISPOSITION: 1–10–56. Default—destruction.

5013. Hemo-Vitonin tablets. (F. D. C. No. 38884. S. No. 23–325 M.)

QUANTITY: 20 100-tablet btls. at Providence, R. I.

SHIPPED: Between 8–22–55 and 11–18–55 from Worcester, Mass.

RESULTS OF INVESTIGATION: Analysis showed that the article contained less than 75 percent of the declared amount of vitamin B_1.

LIBELED: 12–30–55, Dist. R. I.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each tablet contains: * * * Thiamin Chloride (B_1). . . . 2 mg." was false and misleading.

DISPOSITION: 1–24–56. Default—delivered to a charitable institution.

5014. Halazone tablets. (F. D. C. No. 39067. S. No. 36–833 M.)

QUANTITY: 267 cases, 100 100-tablet btls. each, at New York, N. Y.

SHIPPED: During October 1952, from Memphis, Tenn.

LABEL IN PART: (Btl.) "100 Tablets, Water Purification For Treating Water in Canteens * * * Halazone Tablets (p-sulfonedichloramide—benzoic acid 0.004 gm. sodium borate and chloride)" or "100 Water Purification Tablets For Purifying Drinking Water In Canteens * * * N. N. R. (p-sulfonedichloromido—benzoic acid) [or "p-Sulfonedichloramido—Benzoic Acid"] * * * Each tablet contains 0.004 Gm. ($\frac{1}{16}$ grain) of Halazone."

RESULTS OF INVESTIGATION: Analysis showed that the tablets contained from 63 percent to 104.8 percent of the declared amount of halazone. The National Formulary provides that *halazone tablets* contain not less than 90 percent of the labeled amount of halazone.

LIBELED: 5–15–56, S. Dist. N. Y.

CHARGE: 501 (b)—the article purported to be and was represented as "Halazone Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 6–20–56. Default—destruction.

5015. Neuromicrometer device. (F. D. C. No. 36481. S. Nos. 69–736/8 L.)

QUANTITY: 3 devices at Denver, Colo.

SHIPPED: 2 devices were shipped approximately 3 or 4 years prior to the filing of the libel, and 1 device was shipped during January or February 1953, from Logan, Utah, by Standard Instrument Co.

LABEL IN PART: "Neuromicrometer."

ACCOMPANYING LABELING: "Manual of Research Findings In the Biodynamical Basis of Health and Sickness."

RESULTS OF INVESTIGATION: The device was constructed in such a way that it measured electrical resistances, and it was included in the class of instruments known as ohmmeters.

LIBELED: 4–6–54; amended 8–20–54, Dist. Colo.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from, and its quality fell below, that which it purported and was represented to possess.

502 (a)—the labeling accompanying the device, when shipped, contained false and misleading representations that the device was effective for diagnosing sickness in general; the level of cell life; one's health index; one's degree of reserve energy; whether or not one's health was precarious; internal toxicity; one's degree of oxygen consumption; lung ailments; circulatory disorders; debilitating conditions; cell exhaustion; body acidity; acidosis; the degree of chronicity of illness; cell malnutrition; the state of the acid-alkaline balance of the body; irritations; inflammations; pathologies; disease conditions; nervous tendencies; conditions requiring adjustment of the atlas, spine, or pelvis; subluxations; the conditions of the organs and glands; abnormal kidney functioning; pathologies involving local tissues; cell exhaustion due to cancerous invasion; disease conditions of the stomach and liver; carcinogenic ailments; sarcomagenic ailments; cancer; emotional undertones and resentments; psychoses; and location of nerve interference. The accompanying labeling contained the following false and misleading statements, representations, and suggestions (among others):

(1) That under the surface all ailments were the same—a stasis—and their names came only from the stasised tissue involved and the degree of the involvement, rather than etiological factors;

(2) That the *Neuromicrometer* could detect and measure body voltage, body amperage, the body's condenser capacity, variations in the electric potentials of the different parts of the body, and the emotional reactions associated with many ailments;

(3) That body voltage was high in health and low in sickness;

(4) That "All ailments at their onset are over-acid";

(5) That "All Chronic cases of long standing have an over-alkalinity";

(6) That "No cancer case has passed away, except from a heart attack or a hemorrhage, without first becoming highly alkaline"; and

(7) That "When the atlas and the pelvis are adjusted, the two factors more often found to be the offenders in most ailments will have been taken care of."

502 (f) (1)—the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: Dr. George A. Wilson, D. C., claimant, Denver, Colo., filed an answer to the amended libel on 10–13–54; and, on 11–5–54, the answer was amended. On 4–11–56, the Government filed a motion for summary judgment. Thereafter, the Government and the claimant having consented to the entry of the decree without any adjudication as to any issue of fact or law, the court, on 4–24–56, entered an order condemning the devices and ordering that they be delivered to a representative of the Department of Health, Education, and Welfare.

5016. Clinical thermometers. (F. D. C. No. 38939. S. No. 19–556 M.)

QUANTITY: 720 *clinical thermometers* at Cleveland, Ohio.

SHIPPED: 9–16–55 and 11–30–55, from Brooklyn, N. Y., by Cardinal Thermometer Co.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Oral."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Accuracy."

RESULTS OF INVESTIGATION: Examination revealed that 8 out of 24 thermometers taken from this lot failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52 issued by the National Bureau of Standards of the Department of Commerce when tested as described in Commercial Standard CS1–52.

LIBELED: 2–7–56, N. Dist. Ohio.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article when shipped, namely, "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce," was false and misleading.

DISPOSITION: 3–7–56. Default—destruction.

5017. Clinical thermometers. (F. D. C. No. 38921. S. No. 47–488 M.)

QUANTITY: 312 *clinical thermometers* at Newark, N. J.

SHIPPED: 12–10–55, from Brooklyn, N. Y., by Cardinal Thermometer Co.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Oral."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Accuracy."

RESULTS OF INVESTIGATION: Examination revealed that 3 out of 24 thermometers taken from this lot failed to comply with the requirement for accuracy specified in Commercial Standard CS1–52 issued by the National Bureau of Standards of the Department of Commerce when tested as described in Commercial Standard CS1–52.

LIBELED: 1–24–56, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article when shipped, namely, "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce," was false and misleading.

DISPOSITION: 3–5–56. Default—destruction.

5018. Clinical thermometers. (F. D. C. No. 38720. S. No. 29–942 M.)

QUANTITY: 176 *clinical thermometers* in individual cartons at Paterson, N. J.

SHIPPED: Between 12–4–53 and 9–9–55, from Brooklyn, N. Y., by Cornell Instrument Co.

LABEL IN PART: (Carton) "Cornell Fever Thermometer Baby Special."

ACCOMPANYING LABELING: Inserts designated "Certificate of Examination."

RESULTS OF INVESTIGATION: Examination showed that 6 of 24 thermometers taken from this lot failed to meet the labeled standard of accuracy.

LIBELED: 11–28–55, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the label statement "This Certifies that this thermometer has been tested * * * at 98°, 102°, and 106° F. or its equivalent in centigrade scale, and is correct within plus or minus .15° F. or .08° C. at any of these test points" was false and misleading.

DISPOSITION: 1–24–56. Default—destruction.

5019. Clinical thermometers. (F. D. C. No. 38736. S. No. 36–937 M.)

QUANTITY: 64 *clinical thermometers* in envelopes at West New York, N. J.

SHIPPED: 2–9–55 and 3–1–55, from New York, N. Y., by Dependable Thermometer Co.

LABEL IN PART: (Envelope) "Tested Clinical Thermometer Kind Rectal."

ACCOMPANYING LABELING: Inserts designated "Certificate of Examination Fever Thermometer."

RESULTS OF INVESTIGATION: Examination revealed that 2 out of 15 thermometers taken from this lot failed to meet the labeled standard of accuracy.

LIBELED: 12–8–55, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the label statements "This Certifies that the thermometer bearing the above identification number has been tested on the above date at 98°, 102° and 106° F. or its equivalent in centigrade scale, and is correct within plus or minus .20° F. or .11° C. at any of these test points. The accuracy of this thermometer has been determined by testing and checking same with instruments tested by the National Bureau of Standards of the United States Dep't. of Commerce, Washington, D. C." were false and misleading.

DISPOSITION: 1–10–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5020. Salpharin capsules. (F. D. C. No. 38214. S. No. 7–836 M.)

QUANTITY: 480 100-capsule btls. at Oklahoma City, Okla., in possession of C & D Drug Co.

SHIPPED: In March 1955, from Wichita, Kans.

LABEL IN PART: (Btl.) "Salpharin 100 Capsules * * * Active Ingredients: Salicylamide, Aspirin, Ascorbic Acid with Powdered Alfalfa Seed."

ACCOMPANYING LABELING: Leaflets designated "If you suffer discomforts and pain of—Arthritis Rheumatism Lumbago try the new Salpharin Capsules" and loose bottle labels described above.

RESULTS OF INVESTIGATION: The consignee repackaged the capsules into the bottles. The leaflets were printed locally for the consignee.

LIBELED: 7–11–55, W. Dist. Okla.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and

*See also Nos. 5002, 5005, 5008–5013, 5016–5019.

effective treatment for arthritis, rheumatism, neuritis, lumbago, sciatica, neuralgia, and bursitis.

DISPOSITION: C & D Drug Co. appeared as claimant and filed an answer denying that the article was misbranded as alleged. Thereafter, the claimant withdrew its answer; and, on 2–17–56, the court entered a decree condemning the article and ordering that it be destroyed.

5021. Arth-Rite alfalfa capsules. (F. D. C. No. 38265. S. No. 31–206 M.)

QUANTITY: 352 60-capsule btls. at Cleveland, Ohio.

SHIPPED: 6–28–55, from Detroit, Mich., by Carlson Pharmaceuticals, Inc.

LABEL IN PART: (Carton & btl.) "Arth-Rite Alfalfa Plus Vitamins is an effective aid in the relief of ARTHRITIS. * * * Contains P. E. Alfalfa, Vitamin A, Vitamin D, Vitamin B_1 (Thiamine Chloride) Vitamin C, Ferrous Sulfate Dried, Liver Desiccated NF."

ACCOMPANYING LABELING: Circulars entitled "Arth-Rite With Alfalfa."

LIBELED: 8–2–55, N. Dist. Ohio.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for arthritis.

DISPOSITION: 11–17–55. Default—destruction.

5022. Artho-C (Dri-Seal) tablets, BX–B12 (vitamin and mineral) tablets, and Toco-E (tocopherol) capsules. (F. D. C. No. 38731. S. Nos. 9–186/7 M, 9–189 M.)

QUANTITY: Cartons containing 12,100 *Dri-Seal tablets*, 1 drum containing 18,700 *vitamin and mineral tablets*, and 1 drum containing 15,600 *tocopherol capsules*, at Glendale, Calif., in possession of J. G. Alexander, t/a Personal Health Foundation.

SHIPPED: 1–5–55 and 6–15–55, from St. Louis, Mo., and Cleveland, Ohio, to Denver, Colo., and from there to Glendale, Calif., on 9–1–55.

LABEL IN PART: (Carton) "Dri-Seal * * * E. C. Orange Sodium Salicylate, Sodium Paba & Vitamin C" and "Tocopherol Capsules 3 Min.—Round—Clear P. A. D. V.—#7401 Lot No. 2763"; (drum) "V–1 BX–B12 S. C. Vitamins and Minerals"; (box) "100 [or "200" or "300"] Artho-C Tablets * * * Each tablet contains: Sodium Salicylate 250 mg. (4 gr.) Sodium Para-aminobenzoate 250 mg. (4 gr.) Ascorbic Acid (Vitamin C) 20 mg. Distributed by Personal Health Foundation Glendale 5, California," "100 [or "200" or "300"] BX–B12 Improved B-Complex Multi-Vitamin-Mineral Tablets Each 3 Tablets provide: Vitamin A 6,000 Units * * * Vitamin D 600 Units * * * Vitamin E 0.1 mg. * * * Vitamin B1 1.0 mg. * * * Vitamin B2 2.0 mg. * * * Vitamin B6 0.1 mg. * * * Vitamin B12 0.1 mcg. * * * Calcium Pantothenate 1.2 mg. * * * Niacinamide 15 mg. * * * Folic Acid 0.067 mg. * * * Vitamin C 37.5 mg. * * * Calcium 300 mg. * * * Phosphorus 200 mg. * * * Iron 65 mg. * * * Fluorine 0.1 mg. * * * Magnesium 15 mg. * * * Molybdenum 0.1 mg. * * * Copper 1.5 mg. * * * Manganese 3.0 mg. * * * Zinc 3.0 mg. * * * Cobalt 0.3 mg. * * * Iodine 0.15 mg. * * * Distributed by Personal Health Foundation Glendale 5, California * * * As a dietary supplement," and "100 [or "200" or "300"] New Improved Toco-E Capsules A concentrated source of Vitamin E as derived from natural sources (mixed tocopherols). Each capsule contains: dl, alpha tocopheryl acetate 30 mg. equivalent in potency

by biological assay to 30 Units Vitamin E. Distributed by Personal Health Foundation Glendale 5, California."

ACCOMPANYING LABELING: Pamphlets entitled "Personal Health Foundation Price List."

RESULTS OF INVESTIGATION: The drugs were shipped in interstate commerce in bulk, and, upon their receipt, the consignee repacked the *Dri-Seal tablets* into boxes labeled, in part, "Artho-C Tablets"; the *vitamin and mineral tablets* into boxes labeled, in part, "BX–B12 Improved B-Complex Multi-Vitamin-Mineral Tablets"; and the *tocopherol capsules* into boxes labeled, in part, "Toco-E Capsules."

The accompanying labeling was printed for the consignee's use in promoting the sale of the drugs.

LIBELED: 12–13–55, S. Dist. Calif.

CHARGE: 502 (a)—the labeling of the articles, while held for sale, contained false and misleading representations that the *Artho-C (Dri-Seal) tablets* were an adequate and effective treatment for arthritis, rheumatism, bursitis, and neuritis; that the *BX–B12 (vitamin and mineral) tablets* would insure vibrant health, were effective as a tonic, would rejuvenate the red blood cells, would restore strength and give vitality and buoyant energy, were an adequate and effective treatment for nervousness, irritability, tiredness, rheumatic conditions, digestive disturbances, backache, distress over heart and stomach, premature graying, dry hair and scalp, neuritis, leg cramps, headache, dizziness, and mental depression, were effective in preventing colds, were effective in the prevention or treatment of sterility in males, would prevent weakness, restlessness, and pains in muscles and joints, would prevent pyorrhea, bleeding gums, tooth decay, loosened teeth, pale appearance, coughs, and colds, and were effective in the treatment of muscular weakness, nighttime restlessness, uneasy, indisposed feeling, stiff, painful back, and rheumatic pains: and that the *Toco-E (tocopherol) capsules* were adequate and effective in the prevention and treatment of sterility in males and would insure virility in males.

DISPOSITION: 2–2–56. Default—destruction.

5023. Artho-C (Dri-Seal) tablets, BX–B12 (vitamin and mineral) tablets, Nu-Vi-Tal (L–2) tablets, and Toco-E capsules. (F. D. C. No. 38967. S. Nos. 9–191/3 M, 9–195 M.)

QUANTITY: 1 drum containing 4,800 tablets, 1 100-tablet box, and 2 200-tablet boxes of *Artho-C tablets;* 1 drum containing 6,900 tablets, 14 100-tablet boxes, and 40 200-tablet boxes of *BX–B12 tablets;* 1 drum containing 24,280 tablets, 19 100-tablet boxes, 18 200-tablet boxes, and 81 48-tablet boxes of *Nu-Vi-Tal tablets;* and 47 100-capsule boxes, 16 200-capsule boxes, and 3 300-capsule boxes of *Toco-E capsules*, at Glendale, Calif., in possession of J. G. Alexander, t/a Personal Health Foundation.

SHIPPED: Between 6–9–55 and 12–22–55, from Detroit, Mich., and St. Louis, Mo.

LABEL IN PART: (Drum) "Dri-Seal * * * E. C. Orange Sodium Salicylate, Sodium Paba & Vitamin C," "V–1 S. C. Vitamins and Minerals," and "L–2 S. C. Methionine, Choline, Inositol w/B-Complex"; (box) "Artho-C Tablets * * * Each tablet contains: Sodium Salicylate 250 mg. (4 gr.) Sodium Para-aminobenzoate 250 mg. (4 gr.) Ascorbic Acid (Vitamin C) 20 mg. Distributed by Personal Health Foundation Glendale 5, California," "BX–B12 Improved B-Complex Multi-Vitamin-Mineral Tablets Each 3 Tablets provide: Vitamin A 6,000 Units * * * Vitamin D 600 Units * * * Vita-

min E 0.1 mg. * * * Vitamin B1 1.0 mg. * * * Vitamin B2 2.0 mg. * * * Vitamin B6 0.1 mg. * * * Vitamin B12 0.1 mcg. * * * Calcium Pantothenate 1.2 mg. * * * Niacinamide 15 mg. * * * Folic Acid 0.067 mg. * * * Vitamin C 37.5 mg. * * * Calcium 300 mg. * * * Phosphorus 200 mg. * * * Iron 65 mg. * * * Fluorine 0.1 mg. * * * Magnesium 15 mg. * * * Molybdenum 0.1 mg. * * * Copper 1.5 mg. * * * Manganese 3.0 mg. * * * Zinc 3.0 mg. * * * Cobalt 0.3 mg. * * * Iodine 0.15 mg. * * * As a dietary supplement," "New Improved Nu-Vi-Tal Capsule–Tabs A Special Dietary Supplement Each 3 tablets contain: Choline Bitartrate 250 mg. * * * dl, Methionine 150 mg. * * * Inositol 100 mg. * * * Niacinamide 15 mg. * * * Vitamin B1 1.5 mg. * * * Vitamin B2 1.0 mg. * * * Vitamin B6 0.1 mg. * * * d, Calcium Pantothenate 2.0 mg. * * * B-Cotrate (Special yeast conc. 1:7) 100 mg. * * * Liver Powder (Desiccated) 100 mg.," and "New Improved Toco-E Capsules A concentrated source of Vitamin E as derived from natural sources (mixed tocopherols). Each capsule contains: dl, alpha tocopheryl acetate 30 mg."

ACCOMPANYING LABELING: Pamphlets entitled "Personal Health Foundation Price List" and form letters designated "Good News About Amazing Magnesium—Also Help for 'Nerves' and Sex Problems."

RESULTS OF INVESTIGATION: The drugs were shipped in interstate commerce in bulk, and, upon their receipt, the consignee repacked a portion of the *Dri-Seal tablets* into boxes labeled, in part, "Artho-C Tablets"; a portion of the *vitamin and mineral tablets* into boxes labeled, in part, "BX–12"; and a portion of the *L–2 tablets* into boxes labeled, in part, "Nu-Vi-Tal." The *Toco-E capsules* had been repackaged from a lot of capsules which contained d-alpha-tocopheryl acetate.

The accompanying labeling was printed locally for the consignee's use in promoting the sale of the drugs.

LIBELED: 2–27–56, S. Dist. Calif.

CHARGE: 502 (a)—the labeling of the articles, while held for sale, contained false and misleading representations that the *Artho-C* (*Dri-Seal*) *tablets* were an adequate and effective treatment for arthritis, rheumatism, bursitis, and neuritis; that the *BX–B12* (*vitamin and mineral*) *tablets* were effective to insure vibrant health, were an effective tonic, would rejuvenate the red blood cells, would restore strength and give vitality and buoyant energy, were an adequate and effective treatment for nervousness, irritability, tiredness, rheumatic conditions, digestive disturbances, backache, distress over heart and stomach, premature graying, dry hair and scalp, neuritis, leg cramps, headache, dizziness, and mental depression, were effective in preventing colds, were effective in the prevention or treatment of sterility in males, would prevent weakness, restlessness, and pains in muscles and joints, would prevent pyorrhea, bleeding gums, tooth decay, loosened teeth, influenza, kidney stones, pale appearance, coughs, and colds, and were effective in the treatment of muscular weakness, nighttime restlessness, uneasy, indisposed feeling, stiff, painful back, and rheumatic pains; that the *Nu-Vi-Tal* (*L–2*) *tablets* were effective to fight advancing age and old age, would assure greater energy, vitality, and vigorous health for men and women over forty, would prevent hardening of the arteries and heart disease, were effective in the treatment of pain and numbness in the legs or arms, cramps, backache, weakened eyesight, deafness, headaches, dizziness, nervousness, sleeplessness, indigestion, fatigue, and mental depression, and would increase the life span and assure

active zestful living; and that the *Toco-E capsules* were effective in the prevention and treatment of sterility in males and were effective to insure virility in males.

DISPOSITION: 3–28–56. Default—destruction.

5024. Ulceral. (F. D. C. No. 38465. S. No. 7–856 M.)

QUANTITY: 20 cases, 12 btls. each, at Oklahoma City, Okla., in possession of Midwestern Research Laboratories, Inc.

SHIPPED: 8–31–55, from Dallas, Tex., by Midwestern Research Laboratories, Inc.

LABEL IN PART: (Btl.) "Net Contents 16 Fl. Oz. Ulceral * * * Active Ingredients Pepsin, Sarbital, Elixer Vinum Q. S., Arginine, Histidine, Lysine, Tyrosine, Tryptophane, Phenylalanine, Cystine, Methionine, Leucine, Isoleucine, Valine, Threonine."

ACCOMPANYING LABELING: Leaflets designated "Introducing Ulceral" and "What's it done? Ulceral."

LIBELED: 9–27–55, W. Dist. Okla.

CHARGE: 502 (a)—the labeling of the article, when shipped and while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers, dyspepsia, nausea, gastritis, heartburn, indigestion, stomach pain, and excess acidity.

DISPOSITION: 1–5–56. Default—destruction.

5025. Aletris cordial. (F. D. C. No. 38909. S. No. 343 M.)

QUANTITY: 34 7-oz. btls. at Ponce, P. R.

SHIPPED: 8–11–55, from New York, N. Y., by Charles C. Noriega & Co.

LABEL IN PART: (Btl.) "Aletris Cordial * * * A Compound Content Of Alcohol 27.8 Percent * * * Formula: Each fluid ounce represents ten grains Aletris, thirty grains Helonias and thirty grains Scrophularia. * * * Rio Chemical Co. New York."

LIBELED: 1–17–56, Dist. P. R.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that it was an adequate and effective treatment for functional menstrual disturbances, such as painful menstruation.

DISPOSITION: 2–13–56. Default—destruction.

5026. Rutinfusion. (F. D. C. No. 38115. S. No. 5–471 M.)

INFORMATION FILED: 7–13–55, Dist. N. J., against Merit Food Co., Inc., East Paterson, N. J., and Paul R. Neuman.

SHIPPED: 2–25–55, from New Jersey to Illinois.

LABEL IN PART: (Pkg.) "Merit Rutinfusion Sole Distributor Merit Food Co., Inc. 890 River Drive East Paterson, N. J. Weight 2 Oz. Net."

ACCOMPANYING LABELING: Circulars entitled "RUTINFUSION makes 'Life as on a Summer's Day'" and "Rutinfusion (Technical Information)."

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations and suggestions that the article would be an adequate and effective treatment for overcoming capillary fragility; maintaining and restoring normal capillary strength; overcoming hypertension; preventing vascular accidents such as paralytic strokes; maintaining normal

capillary strength for persons receiving medical treatment with thiocyanate drugs, salicylate drugs, and arsenical drugs; controlling pulmonary hemorrhage; overcoming internal bleeding; reducing the feeling of strain and fatigue after heavy or prolonged effort; strengthening the tiny blood vessels of the brain and body so that they may resist the effect of atomic fission; overcoming bodily failure after middle age; preventing premature decay; overcoming paralytic strokes caused by high blood pressure, eye conditions due to high blood pressure, and all forms of weakness of the circulatory system; preventing apoplexy and retinal hemorrhage; controlling gastric hemorrhage and bleeding from the gums; preventing or delaying the advent of many ailments associated with age; asthma; and strengthening and toning up the whole circulatory system, leaving the blood vessels vigorous and elastic.

PLEA: Guilty.

DISPOSITION: 3–16–56. Corporation fined $500; Neuman sentenced to 1 year in jail.

5027. Apple juice concentrate and Rutinfusion. (F. D. C. No. 38964. S. Nos. 21–245/6 M.)

QUANTITY: 22 1-qt. btls. of *apple juice concentrate* and 10 2-oz. boxes of *Rutinfusion* at Oklahoma City, Okla.

SHIPPED: 3–3–55 and 9–15–55, from East Paterson, N. J., by Merit Food Products, Inc.

LABEL IN PART: (Btl.) "Diet-Wise Pure Apple Juice Concentrate"; (box) "Merit rutinfusion (Contains Natural Rutin) * * * Rutinfusion is specially grown and processed leaves and flowers of the buckwheat plant."

ACCOMPANYING LABELING: Pamphlets entitled "Tempting Apple Concentrate."

LIBELED: 2–27–56, W. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the *apple juice concentrate* was effective as a detoxifier; that it was effective to prevent the basic cause of disease, the adverse effects of toxins in the body due to (1) disturbed metabolism, (2) the ingestion of decomposed foods, of foods containing deleterious chemicals, and of drugs, and (3) bacterial invasions of the body; and that it was effective to prevent aches and pains, irritability and general malaise, degenerative changes of the mucous membranes and connective tissues, symptoms resembling arthritis and rheumatism, blood disorders, and the premature emptying of the uterus.

502 (a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the *Rutinfusion* was an adequate and effective treatment for overcoming capillary fragility, maintaining and restoring normal capillary strength, overcoming hypertension, preventing vascular accidents such as paralytic strokes, maintaining normal capillary strength for persons receiving medical treatment with thiocyanate drugs, salicylate drugs, and arsenical drugs, controlling pulmonary hemorrhage, overcoming internal bleeding, and reducing the feeling of strain and fatigue after heavy or prolonged effort.

DISPOSITION: 4–18–56. Default—destruction.

5028. Apple juice concentrate. (F. D. C. No. 38965. S. No. 34–073 M.)

QUANTITY: 7 cases, 12 1-qt. btls. each, at Tulsa, Okla.

SHIPPED: 10–6–55, from East Paterson, N. J., by Merit Food Products, Inc.

LABEL IN PART: (Btl.) "Merit Pure Apple Juice Concentrate."

ACCOMPANYING LABELING: Pamphlets entitled "Tempting Apple Concentrate."

LIBELED: 2–28–56, N. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective as a detoxifier; that it was effective to prevent the basic cause of disease, the adverse effects of toxins in the body due to (1) disturbed metabolism, (2) the ingestion of decomposed foods, of foods containing deleterious chemicals, and of drugs, and (3) bacterial invasions of the body; and that it was effective to prevent aches and pains, irritability and general malaise, degenerative changes of the mucous membranes and connective tissues, symptoms resembling arthritis and rheumatism, blood disorders, and the premature emptying of the uterus.

DISPOSITION: 3–23–56. Default—destruction.

5029. Apple juice concentrate. (F. D. C. No. 38668. S. No. 14–067 M.)

QUANTITY: 45 1-qt. btls. at Little Rock, Ark.

SHIPPED: 5–18–55, from East Paterson, N. J., by Merit Food Co., Inc.

LABEL IN PART: (Btl.) "Diet-Wise Pure Apple Juice Concentrate * * * Distributed By Diet-Wise Foods Company, 127 Prospect St. Passaic, N. J."

ACCOMPANYING LABELING: Pamphlets entitled "Tempting Apple Concentrate."

LIBELED: 11–9–55, E. Dist. Ark.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was effective as a detoxifier; that it was effective to prevent the basic cause of disease, the adverse effects of toxins in the body due to (1) disturbed metabolism, (2) the ingestion of decomposed foods, of foods containing deleterious chemicals, and of drugs, and (3) bacterial invasions of the body; and that it was effective to prevent aches and pains, irritability and general malaise, degenerative changes of the mucous membranes and connective tissues, symptoms resembling arthritis and rheumatism, blood disorders, and the premature emptying of the uterus.

DISPOSITION: 12–19–55. Default—delivered to a charitable institution.

5030. Papay-O-Melon. (F. D. C. No. 38739. S. Nos. 21–236 M, 21–240 M.)

QUANTITY: 42 cases, 12 1-qt. btls. each, at Oklahoma City, Okla.

SHIPPED: Between 9–22–55 and 11–25–55, from St. Augustine, Fla., by Curtis-Sunny Isle Products.

LABEL IN PART: (Btl.) "A Curtis-Sunny Isle Product Homogenized Papay-O-Melon * * * Made from Fresh Ripe Papaya Melons Sugar Added * * * Vitamin Content A, in particular, seems to occur to the extent of 10,000 units to the pound of ripe fruit; B, 7,500 units; C, 7,500 units; G, 10,000 units. * * * Non-Fattening * * * blended scientifically * * * to retain all its essential qualifications and luscious flavor."

RESULTS OF INVESTIGATION: Examination showed that the article was a thick orange-red sirupy liquid containing a substantial amount of sugar, artificial flavor, and artificial color. The product did not have the taste of papaya but resembled in taste an imitation strawberry-flavored beverage.

LIBELED: 12–9–55, W. Dist. Okla.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that it was effective in the treatment of gastric and intestinal disorders, stomach and bowel ailments, constipation, excessive gas, high gastric acidity, stomach and duodenal ulcers, colds, and obesity.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1–13–56. Consent—claimed by Curtis-Sunny Isle Products and relabeled.

5031. Rich Burn Oil and Salcolan. (F. D. C. No. 38638. S. Nos. 4–596/7 M.)

QUANTITY: 6 1-pt. btls., 4 cartons, 12 4-oz. btls. each, 11 cartons, 12 2-oz. btls. each, 17 cartons, 12 1-oz. btls. each, 7 cartons, 12 ½-oz. btls. each, and 1 carton, containing 100 ⅛-oz. btls., of *Rich Burn Oil*, and 6 8-oz. btls. of *Salcolan*, at Eggertsville, N. Y.

SHIPPED: Between 1–1–54 and 6–20–55, from Columbia, Pa., by R & P Products, Inc.

LABEL IN PART: (Btl.) "Rich Burn Oil [or "Salcolan"] * * * Contains Cod Liver Oil, Caraway Oil, Olive Oil, Lanolin and Salol."

ACCOMPANYING LABELING: Leaflets entitled "Tested Proved Accepted Rich Oil" and pamphlets entitled "Instant Cooling Relief Rich Burn Oil."

LIBELED: 10–14–55, W. Dist. N. Y.

CHARGE: 502 (a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that each article was an adequate and effective treatment for all types of burns, scalds, abrasions, and sunburns.

DISPOSITION: 4–12–56. Default—destruction.

5032. Somel Part #1 (soap). (F. D. C. No. 38718. S. No. 1–677 M.)

QUANTITY: 679 bars at Hollywood, Fla., in possession of Albano Lemos, t/a Southern Research Laboratory.

SHIPPED: 6–28–55, from New York, N. Y.

LABEL IN PART: (Bar) "Somel Part #1."

ACCOMPANYING LABELING: Circulars entitled "Hair Free" and "Destroy Unwanted Hair Forever."

RESULTS OF INVESTIGATION: The accompanying labeling was printed in Hollywood, Fla., on the order of the consignee. Examination showed that the article consisted of soap medicated with approximately 2.4 percent resorcinol, 2.5 percent salicylic acid, and 3.5 percent sulfur.

LIBELED: On or about 12–6–55, S. Dist. Fla.

CHARGE: 502 (a)—while the article was held for sale, its accompanying labeling contained false and misleading representations that the article was capable of removing and destroying unwanted hair from the body forever and that, in combination with an ammonia-hydrogen peroxide mixture, it would assure the permanent destruction of unwanted hair; and 502 (e) (2)—when the article was shipped and while held for sale, the label failed to bear the common or usual name of each active ingredient.

DISPOSITION: 1–23–56. Default—destruction.

5033. Hair lotion and hair cream. (F. D. C. No. 38887. S. No. 31–697 M.)

QUANTITY: 798 kits, 1 4-oz. btl. of *hair lotion* and 1 1-oz. jar of *hair cream* each, at Chicago, Ill., in possession of Johannes Item, Inc.

SHIPPED: 9–12–55 and 10–7–55, from Annemasse, France.

LABEL IN PART: (Carton) "Johannes Item Concentrate Hair Lotion Made in France by Ets. M. Martin at Annemasse Joh. Item, Inc. Excl. Distr. U. S. A. Chicago Johannes Item Hair Cream"; (btl.) "Johannes Item Concentrate Hair Lotion * * * Active Ingredients: Nettle leaves and root extract, Oak bark extract, Bur root, Lavender flower extract, 48% alcohol"; (jar) "Johannes Item Hair Cream * * * Act. ingr.: cholesterol, caster oil, salicylic acid, beef marrow, sulphur, nettle root fluid extract."

ACCOMPANYING LABELING: Copies of a printer's proof of a brochure designated "Johannes Item Hair Formula."

RESULTS OF INVESTIGATION: The brochure was printed locally for the consignee.

LIBELED: 1-3-56, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles were an adequate and effective treatment for baldness, excessive loss of hair, dandruff, and all other problem scalp conditions.

DISPOSITION: 2-3-56. Consent—claimed by Johannes Item, Inc. The accompanying labeling was destroyed and the article was relabeled.

5034. Miracold, Mirafume, Miracold dispensers, and accessories. (F. D. C. No. 38502. S. No. 25-286 M.)

QUANTITY: 10 cartoned *Miracold dispensers*, 11 spare *evaporator cones* in individual cartons, 13 *light bulbs* in individual envelopes, 14 btls. of *Miracold*, and 13 btls. of *Mirafume* at Portland, Oreg.

SHIPPED: Between 3-23-55 and 8-3-55, from Everett, Wash., by Little M. D. Co.

LABEL IN PART: (Carton) "Model B The Little MD * * * Miracold Dispenser Designed to combat the common cold, the flu and many other airborne diseases. The Little MD vaporizes Miracold" and "One Little M. D. Evaporator"; (envelope) "One Little MD Lamp 7 w.—120 volts"; (btl.) "Contents 8 Fluid Oz. Miracold Active Ingredient 100% Triethylene Glycol For use in the Little MD * * * Miracold Dispenser" and "Contents 2 fluid ounces Mirafume Air Fragrance (Use sparingly) For use in the Little MD * * * Miracold Dispenser."

ACCOMPANYING LABELING: Leaflets entitled "Directions for Using The Little MD" and "The Little MD Method of Air Sterilization"; reprints entitled "Reprinted From The April, 1948 Hygeia"; and brochures entitled "Glycol Report."

RESULTS OF INVESTIGATION: The dispenser was an electrically operated device for vaporizing liquids.

LIBELED: 1-24-56, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the above-mentioned articles of drug and device, when shipped, contained false and misleading representations that such articles would provide an adequate and effective treatment for, or would prevent, colds, influenza, respiratory ailments, asthma, sinus, hay fever, airborne irritations of the throat and bronchial passages, streptococcal and other infections, virus and bacterial diseases, and diseases caused by airborne pathogens.

DISPOSITION: 5-16-56. Default—delivered to Food and Drug Administration.

5035. Eardrum protectors. (F. D. C. No. 38969. S. No. 36–916 M.)

QUANTITY: 45,000 *rubber earplugs* in 2 cartons, and 325 display cards, each card containing 12 boxes and each box containing 1 pair, of *rubber earplugs*, at New York, N. Y., in possession of E–Z Products (Steckler Sales Co.).

SHIPPED: During 1952 or 1953, from Phoenixville, Pa.

LABEL IN PART: (Carton) "Ear Drum Protectors 679 Red"; (display card) "Improved Protek Ear Drum Protectors"; (unit box) "Protek Improved Ear Drum Protectors."

ACCOMPANYING LABELING: 109,000 empty unit boxes and 425 display cards.

RESULTS OF INVESTIGATION: The devices were shipped in interstate commerce in bulk and were repackaged by the consignee. The unit boxes and display cards were printed locally for the consignee.

The device consisted of two rubber plugs designed so as to fit easily into each ear.

LIBELED: 3–13–56, S. Dist. N. Y.

CHARGE: 502 (a)—the labeling of the device, while held for sale, contained false and misleading representations that it was effective for preventing mastoiditis and other ear infections that might result from engaging in swimming.

DISPOSITION: 3–29–56. Consent—claimed by E–Z Products (Steckler Sales Co.) for relabeling.

5036. Eardrum protectors. (F. D. C. No. 38864. S. No. 38–823 M.)

QUANTITY: 102 display cards, each containing 14 plastic boxes and each box containing 1 pair, of *rubber earplugs* at Miami Beach, Fla.

SHIPPED: 7–12–55, from New York, N. Y., by Eagle Drug Supply Co., Inc.

LABEL IN PART: (Display card) "Fitsrite Audiphone De Luxe Ear Drum Protectors * * * Manufactured By Fitsrite Products Co. New York, N. Y."

ACCOMPANYING LABELING: (Circular enclosed in each box) "Fitsrite 'Audiphone' Ear Drum Protector."

RESULTS OF INVESTIGATION: The device consisted of two rubber plugs so devised as to fit easily into each ear. Inserted in each rubber plug was a small piece of metal in the shape of a cone.

LIBELED: 12–19–55, S. Dist. Fla.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was effective for preventing mastoiditis and ear infections that might result from engaging in swimming.

DISPOSITION: 5–9–56. Default—destruction.

5037. Therapeutic mittens. (F. D. C. No. 38894. S. No. 40–410 M.)

QUANTITY: 32 devices at Minneapolis, Minn.

SHIPPED: 11–22–55, from Middleboro, Mass., by Lobl Mfg. Co.

LABEL IN PART: (Carton) "De Ans Infra-Ray Therapeutic Mittens."

ACCOMPANYING LABELING: Leaflets designated "Now Blessed Relief from the pains of * * *."

RESULTS OF INVESTIGATION: The article consisted of a pair of hand coverings made of rubberized cloth and plastic, in which electrical heating wires were enclosed so that when the plug attached to the mittens was connected with a household electrical outlet, the hand coverings became warm.

LIBELED: 1–9–56, Dist. Minn.

CHARGE: 502 (a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article provided an adequate and effective treatment for arthritis, rheumatism, sinus conditions, nervous conditions, and other ailments where blood stimulation was indicated for the relief of pain, and for excruciating pain accompanying arthritis and rheumatism.

DISPOSITION: 3–1–56. Default—delivered to Food and Drug Administration.

DRUGS FOR VETERINARY USE*

5038. Veterinary drug preparations. (F. D. C. No. 38904. S. Nos. 24–798/9 M.)

QUANTITY: 19 1-lb. cans of *Dr. David Roberts Rx No. 46* and 7 1-lb. cans of *Udder Rx No. 20* at Seattle, Wash.

SHIPPED: Between 3–22–55 and 8–30–55, from Waukesha, Wis., by Dr. David Roberts Veterinary Co.

LABEL IN PART: (Can) "Dr. David Roberts Rx No. 46 For Cows and Heifers at Freshening Time Active Ingredients Nux Vomica (Strychnine one grain in each ounce) Dandelion Root Burdock Root Ginger Root Carbolic Acid 1.2% Other Ingredients Anise Licorice Epsom Salts Sulphur Locust Bean Meal Salt Corn Starch Colombo Root" and "Udder Rx No. 20 An Adjuvant in the Treatment of Mastitis * * * Active Ingredients: Nux Vomica (strychnine .23 grains in each ounce) Potassium Iodide, Poke Root, Iron Sulphate, Sulphur, Colombo Root, Cobalt sulphate. Inert ingredients: Calcium phosphate, Sodium bicarbonate. Enriched yeast products * * * Prepared by Dr. David Roberts Veterinary Co. Waukesha, Wisconsin * * * Mastitis Yields faster when Cobalt steps up the effectiveness of Antibiotic action."

LIBELED: On or about 1–13–56, W. Dist. Wash.

CHARGE: 502 (a)—the labels of the articles, when shipped, contained false and misleading representations that *Dr. David Roberts Rx No. 46* was an adequate and effective treatment for retained placenta; that *Udder Rx No. 20* was an adequate and effective treatment for mastitis, would help arrest inflammation and prevent suppuration, had antibiotic action, and would step up the effectiveness of antibiotics administered in conjunction with it.

DISPOSITION: 3–9–56. Default—destruction.

5039. Master Liquid (2 seizure actions). (F. D. C. Nos. 36149, 36150. S. Nos. 83–852/3 L.)

QUANTITY: 17 1-gal. jugs at Mineral Point, Wis., and 16 1-gal. jugs at Potosi, Wis.

SHIPPED: 9–3–53 and 9–11–53, from Omaha, Nebr., by Master Laboratories, Inc.

LABEL IN PART: (Jug) "Master Liquid * * * Ingredients: Sodium Thio-Sulphate; Beechwood Creosote; Guaiacol; Powdered Extract of Licorice: Sodium Hydroxide 9%; Sodium Bicarbonate; Betanapthol: Oil of Anise; Sodium Phenosulfonate: Solution of Potassium Arsenite, (Arsenic as Arsenous Oxide, 0.75%); Nicotinic Acid."

ACCOMPANYING LABELING: (17-jug lot) Letters addressed to "Dear Friend and Dealer" and "Dear Dealers."

LIBELED: On or about 12–7–53, W. Dist. Wis.

CHARGE: 502 (a)—(both lots) the following statements on the label of the article, when shipped, were misleading since they suggested and implied that

*See also No. 5006.

the article was an effective remedy for diseases of swine, whereas it was not an effective remedy for such diseases: "Master Liquid For Old Hogs and Young Pigs * * * Estimate the largest amount of whole oats your hogs will eat in one day. For every three bushels of whole oats to be fed, mix 1 pint of Master Liquid * * * with 15 gallons of clean water * * *. To this solution add the whole oats and mix well by stirring. * * * Keep the prepared oats in feeding troughs at all times so hogs have free access to them. * * * Follow this practice for the first two weeks. The Third Week: Feed prepared oats in the morning and give other feeds during the remainder of the day. The Fourth Week: The animals can be put back on regular rations and thereafter fed prepared oats two or three days each week. On these days allow no other feed or they can be fed the preparation every morning and other feed the remainder of the day." The representation on the label "Alkalinizes Slops composed of Oats, Barley or Grain Mixtures" also was misleading since the labeling of the article failed to reveal the material fact, in the light of such representation, that, whether or not the article alkalinized slops, such alkalinization was of no value or importance.

502 (a)—(17-jug lot) the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for "necro" of swine and conditions producing runty, unthrifty, and poor doing swine.

DISPOSITION: Master Laboratories, Inc., appeared as claimant in these cases and filed motions for their removal to the United States District Court for the District of Nebraska or the Southern District of Iowa. The Government filed a counter motion to consolidate these two cases and to transfer them to the Northern District of Iowa. Subsequently, the claimant filed an amended motion to consolidate the two actions pending in the Western District of Wisconsin; to consolidate these actions with 6 cases (already consolidated) which were pending in the Northern District of Iowa and to transfer the cases pending in the Northern District of Iowa to the Western District of Wisconsin; and to remove the case as finally consolidated to the Southern District of Iowa.

On 11–30–54, the court ordered the two cases pending in the Western District of Wisconsin to be consolidated for trial, denied the remainder of claimant's motion, and ordered the claimant to file an answer to the libel within 20 days. On 12–22–54, the claimant filed objections to the jurisdiction of the court and a demurrer to the libel on the grounds that it failed to state a cause of action against the article or the claimant.

The Government filed a motion for a default judgment or, in the alternative, for a summary judgment. The Government's motion for a summary judgment was granted on 1–17–56; and, on 1–31–56, the court entered an order condemning the product and ordering that it be destroyed.

5040. Sulfadine and Sulfa-Du. (F. D. C. No. 38992. S. Nos. 14–135/6 M.)

QUANTITY: 16 1-gal. btls. of *Sulfadine* and 1 1-gal. btl. of *Sulfa-Du at* Springdale, Ark.

SHIPPED: 4–14–53 and 12–2–54, from Dallas, Tex., by Hill Poultry Service.

LABEL IN PART: (Btl.) "Chemic Brand Farm Chemistry Associates Sulfadine (Solution of Sulfaguanidine Acid) Each 100 cc. contains 5 Gms. Sulfaguanidine" and "Chemic Brand Farm Chemistry Associates Sulfa-Du (hydrochloride of sulfathiazole) Each 100 cc. contains an equal of 4.5 grams of Sulfathiazole."

LIBELED: 3–15–56, W. Dist. Ark.

CHARGE: 502 (a)—the labels of the articles, when shipped, contained false and misleading representations that the *Sulfadine*, when used as directed, was an adequate and effective treatment for cecal coccidiosis and enteritis in poultry and that the *Sulfa-Du*, when used as directed, was an adequate and effective treatment for infectious coryza and colds in poultry.

DISPOSITION: 5–19–56. Default—destruction.

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PRODUCTS

[1] (5020) Seizure contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5020) Seizure contested.

U. S. GOVERNMENT PRINTING OFFICE: 1957

D. D. N. J., F. D. C. 5041–5060 Issued May 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5041–5060

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement, "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 6, 1957.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

5041. (F. D. C. No. 38558. S. Nos. 21–181/4 M, 21–186/8 M.)

INFORMATION FILED: 1–19–56, W. Dist. Mo., against **Myerly's Pharmacy, Inc., Kansas City, Mo., and Samuel J. Gershon (vice president).**

CHARGE: Between 5–13–55 and 7–9–55, *phenobarbital sodium capsules* were dispensed 5 times and *secobarbital sodium capsules* were dispensed once without a prescription, and *secobarbital sodium capsules* also were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 3–2–56. Corporation fined $35. Individual fined $1,000, plus costs, and sentenced to 3 months in prison; prison sentence suspended and individual placed on probation for 2 years.

5042. (F. D. C. No. 37831. S. Nos. 79–502 L, 79–504 L, 86–491/2 L.)

INFORMATION FILED: 3–10–55, N. Dist. Ohio, against **Nicholas G. Lungociu, t/a Valley Pharmacy, Akron, Ohio.**

CHARGE: Between 1–23–54 and 2–10–54, *tablets and capsules containing a mixture of phenobarbital, hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide* were dispensed a total of 3 times and *dextro-amphetamine sulfate capsules* were dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 3–25–55. $300 fine.

5043. (F. D. C. No. 38143. S. Nos. 59–899 L, 59–904 L, 59–907/8 L.)

INFORMATION FILED: 9–28–55, W. Dist. N. C., against **Kiser Drug Co. (a partnership), Charlotte, N. C., and Edna Puckett (an employee).**

CHARGE: Between 6–11–54 and 6–25–54, *phenobarbital tablets* were dispensed 3 times and *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Nolo contendere—by each defendant to all counts.

DISPOSITION: 10–10–55. Partnership fined $200; Puckett fined $250 and placed on probation for 2 years.

5044. (F. D. C. No. 38125. S. Nos. 5–845 M, 5–849 M, 6–009 M, 6–011 M, 6–544 M.)

INFORMATION FILED: 8–2–55, E. Dist. Tenn., against **George M. Stevens, Jr., t/a Stevens Drug Store, Fountain City, Tenn., and Fred W. Walker (an employee).**

CHARGE: Between 12–7–54 and 1–29–55, *Neo-Sedaphen* (a drug containing pentobarbital sodium and phenobarbital sodium) was dispensed twice and *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty—by Stevens to all counts of the information and by Walker to dispensing *Neo-Sedaphen* twice and *Dexedrine Sulfate tablets* once.

DISPOSITION: 9–1–55. Stevens fined $350; Walker fined $150.

5045. (F. D. C. No. 37879. S. Nos. 68–415/6 L, 71–683 L, 71–689 L, 71–882 L, 71–884 L, 72–102 L, 72–108 L.)

INFORMATION FILED: 7–6–55, Dist. N. J., against **Herman Doctofsky, t/a Weir's Pharmacy, Manasquan, N. J.**

CHARGE: Between 7–13–54 and 8–2–54, *sulfose tablets* were dispensed 3 times, *pentobarbital sodium capsules* and *phenylbutazone tablets* were each dispensed twice, and *Veriloid tablets* were dispensed once upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 9–6–55. $500 fine and probation for 2 years.

5046. (F. D. C. No. 38548. S. Nos. 59–902/3 L, 59–905 L, 60–692 L, 60–754 L, 60–756/7 L.)

INFORMATION FILED: 12–9–55, W. Dist. N. C., against **Harry Lee Bizzell, t/a Bizzell Pharmacy, Charlotte, N. C., and Elbert A. Moffitt (an employee).**

CHARGE: Between 6–21–54 and 7–16–54, *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 3 times (counts 1, 4, and 6) and *dextro-amphetamine sulfate tablets* were dispensed 4 times (counts 2, 3, 5, and 7), without a prescription.

PLEA: Nolo contendere—by Bizzell to all counts and by Moffitt to counts 1, 2, 3, 4, and 6.

DISPOSITION: 4–23–56. Each defendant fined $500.

5047. (F. D. C. No. 38567. S. Nos. 29–121 M, 30–003/6 M, 30–012/14 M.)

INFORMATION FILED: 1–25–56, Dist. N. J., against **Rutherford Drug Store, Inc., Rutherford, N. J., Irving Schiffman (president) and Benjamin Mattes (pharmacist).**

CHARGE: Between 5–13–55 and 6–21–55, a quantity of *Selsun Sulfide suspension* was dispensed without a prescription (count 5); and *phenylbutazone tablets* were dispensed 4 times (counts 1, 4, 7, and 8) and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 3 times (counts 2, 3, and 6) upon request for prescription refills without authorization by the prescribers.

PLEA: Guilty—by corporation to all counts of the information; by Schiffman to counts 2, 3, 4, 5, 6, 7, and 8; and by Mattes to counts 1, 2, and 3.

DISPOSITION: 3–16–56. Corporation fined $500; Schiffman fined $500 and placed on probation for 5 years; Mattes fined $250 and placed on probation for 3 years. Each individual sentenced to imprisonment for 1 year, but execution of sentence suspended.

5048. (F. D. C. No. 37870. S. Nos. 11–809/12 M, 11–818 M, 12–283/4 M.)

INFORMATION FILED: 6–1–55, Dist. N. J., against **Warner Drugs, Inc., Bradley Beach, N. J., and Max M. Warner (president).**

CHARGE: Between 12–15–54 and 1–5–55, *Veriloid tablets* were dispensed once without a prescription, and *Benzedrine Sulfate tablets* were dispensed twice and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were dispensed 4 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 6–24–55. Corporation and individual each fined $250 with respect to 4 counts of the information.

On the remaining 3 counts of the information, the court suspended the sentence against the corporation and placed the individual on probation for 2 years.

5049. (F. D. C. No. 38559. S. Nos. 18–522/4 M, 18–764 M, 18–770/1 M.)

INDICTMENT RETURNED: 4–25–56, S. Dist. N. Y., against **Meyer Wiener and Alex Wiener (partners in, and pharmacists for, Cathedral Chemists), New York, N. Y.**

CHARGE: Between 4–22–55 and 8–2–55, *Bicillin tablets* were dispensed three times, *AM Plus capsules* were dispensed twice, and *Gantrisin tablets* were dispensed once without a prescription.

PLEA: Guilty—by Meyer Wiener to dispensing *Bicillin tablets* twice and *AM Plus capsules* once and by Alex Wiener to dispensing *Bicillin tablets*, *Gantrisin tablets*, and *AM Plus capsules* one time each.

DISPOSITION: 5–4–56. Alex Wiener fined $300 and Meyer Wiener $450.

5050. (F. D. C. No. 38568. S. Nos. 4–947/8 M, 5–049 M, 5–051 M, 5–054/5 M.)

INFORMATION FILED: 1–30–56, N. Dist. Ill., against **Triangle Pharmacy (a partnership), Chicago, Ill., Bernard Rosenbloom (partner and pharmacist), Michael Joseph Rio (employee), and Salvatore Pape (apprentice pharmacist).**

CHARGE: Between 1–7–55 and 1–18–55, *penicillin G potassium tablets* (counts 1 and 5) and *apiol-ergot compound capsules* (counts 2 and 3) were each dispensed twice and *Sec-Amobarb capsules* (count 4) and *Metandren Linguets* (count 6) were each dispensed once, without a prescription.

PLEA: Guilty—by partnership to all counts of the information; by Rosenbloom to counts 1, 2, and 3; by Rio to counts 4 and 6; and by Pape to count 5.

DISPOSITION: 3–7–56. Partnership fined $100; Rosenbloom, $500, plus costs; Rio, $200; and Pape, $100.

5051. (F. D. C. No. 38584. S. Nos. 35–706 M, 35–708/10 M.)

INFORMATION FILED: 2–29–56, N. Dist. Ill., against **Barry's Cut Rate Stores, Inc., Chicago, Ill., and Edward Golin (president, manager, and pharmacist).**

CHARGE: Between 7–5–55 and 8–5–55, *Savatan capsules* were dispensed once and *Pentids tablets* were dispensed three times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 3–20–56. Corporation fined $100, plus costs; individual fined $250.

5052. (F. D. C. No. 38561. S. Nos. 13–202/3 M, 13–205/9 M.)

INFORMATION FILED: 1–31–56, E. Dist. Pa., against **Maxwell Zalstein, t/a Physicians' Pharmacy, Philadelphia, Pa.**

CHARGE: Between 12–10–54 and 1–14–55, *chlortetracycline capsules* and *capsules containing apiol and ergot* were each dispensed twice and *penicillin tablets*, *oxytetracycline hydrochloride capsules*, and *tablets containing erythromycin stearate with triple sulfas* were each dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–9–56. $2,100 fine; jail sentence for 3½ years suspended and defendant placed on probation for 5 years.

5053. (F. D. C. No. 37825. S. No. 58–672 L.)

INFORMATION FILED: 4–7–55, E. Dist. Mich., against **Eugene H. Smith, t/a Canfield Cut Rate Drug, Detroit, Mich.**

CHARGE: On 4–1–54, *oxytetracycline hydrochloride capsules* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 7–5–55. $500 fine.

5054. (F. D. C. No. 38607. S. Nos. 23–127 M, 23–130 M.)

INFORMATION FILED: 6–6–56, Dist. Mass., against **Barone Bros., Inc., Boston, Mass., and Arthur R. Januario (president).**

CHARGE: Between 8–16–55 and 10–11–55, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 8–16–56. Corporation—$250 fine. Individual—$150 fine; jail sentence for 6 months suspended and individual placed on probation for 1 year.

5055. (F. D. C. No. 38507. S. Nos. 11–101/2 M.)

INFORMATION FILED: 11–22–55, W. Dist. Tex., against **Howard G. Harmon, t/a Harmon's Health Service, San Antonio, Tex., and Paul F. Harmon (an employee).**

CHARGE: Between 8–1–54 and 11–13–54, *Rauwoltin tablets* and *Rauwolfia serpentina tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Howard G. Harmon to dispensing both drugs and by Paul F. Harmon to dispensing *Rauwoltin tablets.*

DISPOSITION: 12–12–55. Each defendant fined $100.

5056. (F. D. C. No. 37830. S. Nos. 63–088 L, 63–751 L, 63–951 L, 72–780 L, 72–785 L, 72–790 L.)

INFORMATION FILED: 4–1–55, E. Dist. Ill., against **Douglas Drug Co. (a partnership), Mt. Vernon, Ill., Douglas A. Sapper, Sr., and Douglas A. Sapper, Jr. (partners in the partnership), and Doran Laverne Kernodle (a pharmacist for the partnership).**

CHARGE: Between 9–3–54 and 10–11–54, *diethylstilbestrol tablets* (counts 1 and 3) and *sulfisoxazole tablets* (counts 5 and 6) were each dispensed twice and *thyroid tablets* (count 2) were dispensed once without a prescription, and *dextro-amphetamine sulfate capsules* (count 4) were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by partnership to all 6 counts of the information; by Douglas A. Sapper, Sr., to counts 1, 2, 3, and 4; by Douglas A. Sapper, Jr., to count 5; and by Doran Laverne Kernodle to count 6.

DISPOSITION: 4–19–55. Fine of $600 against partnership, $400 against Douglas A. Sapper, Sr., $100 against Douglas A. Sapper, Jr., and $100 against Doran Laverne Kernodle. The fine against the partnership was abated by the fines against the individuals.

5057. (F. D. C. No. 37836. S. Nos. 89–296 L, 89–308 L, 14–081/2 M.)

INFORMATION FILED: 4–11–55, W. Dist. Ark., against **Joe H. Gibbs (a pharmacist and partner in the Gannaway Drug Store), Warren, Ark.**

CHARGE: Between 8–24–54 and 11–1–54, *sulfisoxazole tablets* were dispensed once without a prescription, and *Dexedrine Spansule capsules* were dispensed 3 times upon requests for prescription refills without authorization by the prescribers.

PLEA: Nolo contendere.

DISPOSITION: 6–2–55. Defendant placed on probation for 1 year.

5058. (F. D. C. No. 37842. S. Nos. 10–776/8 M.)

INFORMATION FILED: 5–3–55, S. Dist. Tex., against **James W. Stone, t/a North Houston Pharmacy, Houston, Tex., and Robert C. Miles (pharmacist).**

CHARGE: Between 12–1–54 and 12–4–54, *sulfathiazole tablets* were dispensed three times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial by jury on 10–5–55; and, on 10–7–55, the jury returned a verdict of not guilty as to James W. Stone and guilty as to Robert C. Miles. On 10–14–55, Miles was sentenced to 6 months in jail, which sentence was suspended, and placed on probation for 3 years.

5059. (F. D. C. No. 37187. S. Nos. 68–171 L, 68–173 L.)

INFORMATION FILED: 1–26–55, N. Dist. Ala., against **Robert Harbin, t/a Robert Harbin Pharmacy, Birmingham, Ala.**

CHARGE: Between 5–28–54 and 6–11–54, *cortisone acetate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–12–55. $250 fine.

5060. (F. D. C. No. 37258. S. Nos. 82–052 L, 82–054 L, 82–056/7 L, 82–059/61 L.)

INFORMATION FILED: 4–6–55, Dist. Nebr., against **Louis J. Kohll, t/a Park Avenue Drugs, Omaha, Nebr., and Everett O. Drake (a pharmacist).**

CHARGE: Between 9–10–54 and 10–11–54, a number of *gray, pink, and blue tablets containing, among other ingredients, desoxyephedrine, thyroid, atropine sulfate, aloin, and phenobarbital* were dispensed at 6 different times and a number of *Pentid-Sulfas tablets* were dispensed once, without a prescription.

PLEA: Nolo contendere—by Kohll to all 7 counts of the information and by Drake to 4 counts.

DISPOSITION: 9–8–55. Kohll fined $175, plus costs, and Drake $100, plus costs.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5058) Prosecution contested.

[1] (5058) Prosecution contested.

[1] (5058) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1957

D. D. N. J., F. D. C. 5061–5080 Issued November 1957

U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5061–5080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default or consent; (2) criminal proceedings which were terminated with a plea, finding, or verdict of guilty, or a plea of nolo contendere; (3) injunction proceedings terminated with the entry of an injunction; (4) contempt proceedings for violation of an injunction, which were terminated upon a plea of guilty. Included are a number of cases adjudicated earlier than those now being recorded in current notices of judgment, but not published because complete records were not available immediately after the cases were terminated. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal, injunction, and contempt proceedings are against the *firms or individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 12, 1957.*

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*For cosmetic actionable under the drug provisions of the Act, see No. 5075.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D. D. N. J. NOS. 5061–5080

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess; Section 501 (d) (2), the article was a drug, and a substance had been substituted wholly or in part therefor.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

New-drug violation, Section 505 (a), the article was a new drug within the meaning of Section 201 (p), which was introduced into interstate commerce, and an application filed pursuant to Section 505 (b) was not effective with respect to such drug.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

5061. Honey with Royal Jelly. (F. D. C. No. 39022. S. No. 33–991 M.)

QUANTITY: 17 1-lb., 8-oz. jars, at Tulsa, Okla., in possession of Akin Natural Food.

SHIPPED: 2–29–56, from Los Angeles, Calif., by Western Commerce Corp.

LABEL IN PART: (Jar) "Topaz Brand Cream Of The Tropics Honey With Royal Jelly Wonder Food Of The Queen Bee Each teaspoonful contains approx. 100 mg. of Royal Jelly."

ACCOMPANYING LABELING: (Leaflet) "Royal Jelly by R. B. Willson."

RESULTS OF INVESTIGATION: The above-mentioned leaflet was printed locally for the consignee.

LIBELED: 4–6–56; amended 5–22–56, N. Dist. Okla.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for nervous and glandular disorders, including aging, cerebral neuritis, arthritis, autointoxication from tobacco, asthma, failing eyesight, sterility in women, impotence in men, and deficient lactation in women; and 505 (a)—the article was a new drug which may not be lawfully introduced into interstate commerce since an application filed pursuant to law was not effective with respect to the drug.

DISPOSITION: 6–12–56. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

5062. Elemin vitamin and mineral tablets. (F. D. C. No. 37266. S. No. 5–566 M.)

INFORMATION FILED: 8–3–55, E. Dist. Wis., against John P. Sheeran, Milwaukee, Wis.

ALLEGED VIOLATION: 11–16–54, the defendant, in the course of a sales talk to an individual, made oral representations holding out the article as an effective treatment for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded while held for sale.

LABEL IN PART: (Carton) "Elemin Supreme Formula G & J Multiple Vitamins This Package Contains a 60 Day Supply SUPREME FORMULA is packaged in sanitary, hermetically sealed Pocket Paks, each containing 2 Elemin Mineral Tablets and 1 G & J Multiple Vitamin Tablet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, colds, sinus infections, heart trouble, diabetes, asthma, high blood pressure, ulcerated stomach, and arthritis.

PLEA: Not guilty.

DISPOSITION: The case came on trial before the court without a jury on 2–17–56, and was concluded on the same day. The court took the case under advisement; on 3–28–56, the court handed down a finding of guilty against the defendant. On 6–18–56, the court suspended imposition of sentence and placed the defendant on probation for 1 year.

5063. Vitamin and mineral food supplement. (F. D. C. No. 38452. S. Nos. 7854/5 M.)

QUANTITY: 46 cases, each containing 12 packages and each package containing 1 186-tablet bottle of *mineral tablets* and 1 62-capsule bottle of *vitamin capsules*, at Oklahoma City, Okla., in possession of K. V. Products Co.

SHIPPED: 7–29–55, from Glendale, Calif.

LIBELED: 9–20–55, W. Dist. Okla.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which the article was intended, namely, in the treatment of rheumatism, asthma, heart conditions, loss of hair, nosebleed, and for cleaning the blood, which were the conditions and purposes for which the article was offered orally by Mrs. Bertha Lee Wilson, a representative of K. V. Products Co.

DISPOSITION: 6–7–56. Default—destruction.

5064. Cal-O-Dine. (F. D. C. No. 38461. S. No. 24–750 M.)

QUANTITY: 26 2-qt. jugs at Seattle, Wash., in possession of Emil Gellerman.

SHIPPED: 8–15–55, from Alameda, Calif.

LABEL IN PART: "Cal-O-Dine * * * A Dietary Source of Iodine Consists of Potassium Iodide In Processed Sea Water."

LIBELED: 9–29–55, W. Dist. Wash.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of heart disease, arthritis, stomach troubles, ulcers, paralysis, cataracts, tumors, dizzy spells, pernicious anemia, goiters, burns, and bruises, which were the conditions for which the article was offered by Emil Gellerman.

DISPOSITION: 8–28–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5065. Various drugs. (Inj. No. 280.)

COMPLAINT FOR INJUNCTION FILED: 4–29–54, E. Dist. N. Y., against Bonded Laboratories, Inc., Brooklyn, N. Y., and Hans Lowey, president of the corporation.

CHARGE: The complaint alleged that the defendants had been and still were engaged in manufacturing, selling, and shipping directly to places outside the State of New York, and delivering to a Brooklyn firm for shipment to places outside the State of New York, various drugs which were adulterated and misbranded as follows:

501 (b)—a portion of the drugs purported to be and were represented as drugs, the names of which are recognized in official compendia, namely, the United States Pharmacopeia and the National Formulary; and the strength of the drugs differed from the standards set forth in such compendia;

501 (c)—the strength of a portion of the drugs differed from that which they purported and were represented to possess;

501 (d) (2)—certain substances had been substituted for a portion of the drugs;

502 (a)—the labeling of a portion of the drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs.

The complaint alleged further that the adulterated and misbranded conditions of the drugs resulted from deficiencies in the ingredients of the drugs, the presence of ingredients in amounts in excess of those declared on the labels or required by the standards set forth in the official compendia, and the substitution of certain substances for the drugs involved.

For example, examination of samples from interstate shipment and from deliveries for interstate shipment made by the defendants of certain articles of drugs, namely, *Visnico Pulvoids*, *Siccoid hematinic tablets*, *sulfadiazine tablets*, *aminophylline-phenobarbital tablets*, *diethylstilbestrol tablets*, *ammonium chloride tablets*, *phenobarbital tablets*, *Dietabs No. 1*, *Dietabs No. 2*, and *Dietabs No. 3*, disclosed that the *Visnico Pulvoids* contained only 68 percent of the declared amount of potassium nitrate and not more than 77 percent of the declared amount of sodium nitrate; that the *Siccoid hematinic tablets* contained not more than 66 percent of the declared amount of vitamin C; that two lots of the *sulfadiazine tablets* were not only deficient in sulfadiazine to the extent that they contained from 20 percent to 21.2 percent of the declared amount of sulfadiazine, but they were also of a different composition from that declared on their labels by reason of the substitution in part of a large amount of sulfathiazole for the sulfadiazine ingredient; that one other lot of the *sulfadiazine tablets* contained less than 80 percent of the declared amount of sulfadiazine; that the *aminophylline-phenobarbital tablets* contained at least 19 percent more phenobarbital than the ¼ grain of phenobarbital declared on the label and at least 10 percent more aminophylline than the 1½ grain of aminophylline declared on the label; that the *diethylstilbestrol tablets* contained 73.4 percent of the declared amount of diethylstilbestrol; that the *ammonium chloride tablets* contained not more than 68 percent of the declared amount of ammonium chloride; that the *phenobarbital tablets* contained 27 percent more phenobarbital than the ½ grain of phenobarbital declared on the label; that the *Dietabs No. 1* contained not more than 61.2 percent of the declared amount of amphetamine sulfate; that the *Dietabs No. 2* contained not more than 54.6 percent of the declared amount of amphetamine sulfate; and that the *Dietabs No. 3* contained not more than 62.4 percent of the declared amount of amphetamine sulfate.

The complaint alleged further that the defendants were well aware that their activities were violative of the Act. Several inspections were made of the defendants' plant in Brooklyn, N. Y., by inspectors of the Food and Drug

Administration between 2–13–51 and 2–8–54, at which times the defendants were informed of certain inadequacies in their control system for the manufacture of the articles, namely, the failure to assay the raw materials used; the lack of care in identifying containers of raw materials, batches of the articles during processing, and the finished articles; the lack of an adequate checking system to insure that the proper amounts of the various chemicals were put into the batches of the chemicals being processed; and the practice of making very few assays of the finished articles. The defendants were warned that such inadequacies would result in errors of composition and labeling with respect to the articles manufactured, and that such inadequacies would result also in the articles being adulterated and misbranded as aforesaid. The defendants had been warned also by 4 seizures and by a notice of hearing. Despite such warnings, the defendants continued to introduce and deliver for introduction into interstate commerce drugs which were adulterated and misbranded as described above.

The complaint alleged also that certain vitamin preparations were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 23244.

DISPOSITION: On 4–29–54, the court entered a temporary restraining order under which the defendants were temporarily restrained from commission of the acts complained of. Thereafter, with the consent of the parties, the temporary restraining order was continued in effect pending the final determination of the matter.

On 12–12–55, a consent decree of permanent injunction was entered against Bonded Laboratories, Inc., its agents, servants, employees, and representatives, and all and any persons in active concert or participation with them, and against the president of Bonded Laboratories, Inc., whether in connection with such corporation or independently, enjoining them against introducing or delivering for introduction into interstate commerce any foods and drugs which are adulterated and misbranded as charged in the complaint, and which are manufactured, prepared, and packed by Bonded Laboratories, Inc., without the utilization of good controls necessary to the end that an article of proper composition is purchased and shipped.

5066. Aspirin tablets. (F. D. C. No. 35661. S. No. 52–623 L.)

QUANTITY: 2 50,000-tablet drums at Greystone Park, N. J.

SHIPPED: 7–14–53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LIBELED: 9–25–53, Dist. N. J.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Aspirin Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its quality and purity fell below the standard set forth in such compendium in that the article had a strong odor of acetic acid, many of the tablets were discolored, and a portion of the tablets contained less than 5 grains of acetylsalicylic acid.

DISPOSITION: 10–30–53. Default—destruction.

5067. Sulfadiazine tablets and diethylstilbestrol tablets. (F. D. C. No. 36103. S. Nos. 50–555 L, 50–557 L.)

QUANTITY: 17 100-tablet btls. of *sulfadiazine tablets* and 33 100-tablet btls. of *diethylstilbestrol tablets* at Newark, N. J.

SHIPPED: 7–2–53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LABEL IN PART: (Btl.) "100 Tablets List 525 Quality R/W Products Sulfadiazine (2-Sulfanilamidopyrimidine) 7.7 Grains (0.5 Gm.)" and "100 Tablets List 340 Diethylstilbestrol 5 Mg."

RESULTS OF INVESTIGATION: Analyses showed that the *sulfadiazine tablets* contained not more than 78.3 percent of the labeled amount of sulfadiazine and that the *diethylstilbestrol tablets* contained not more than 76.4 percent of the labeled amount of diethylstilbestrol.

LIBELED: 11–9–53, Dist. N. J.

CHARGE: *Sulfadiazine tablets.* 501 (b)—the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its strength differed from, and its quality fell below, the official standard since the article contained less than 95 percent of the labeled amount of sulfadiazine, the minimum permitted by the standard, and the article failed to meet the test for individual weight variation for tablets as prescribed in the standard.

Diethylstilbestrol tablets. 501 (b)—the article purported to be and was represented as a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its strength differed from the official standard since the article contained less than 90 percent of the labeled amount of diethylstilbestrol, the minimum permitted by the standard.

DISPOSITION: 12–16–53. Default—destruction.

5068. Clinical thermometers. (F. D. C. No. 38960. S. Nos. 1–849 M, 1–875/6 M.)

QUANTITY: 195 *clinical thermometers* at Wilmington, N. C.

SHIPPED: 12–22–55, from New York, N. Y., by Affiliated Drug Stores, Inc.

LABEL IN PART: (Box) "Cardinal Fever Thermometer Kind—Rectal [or "Oral"]."

ACCOMPANYING LABELING: Leaflets designated "Certificate of Accuracy For Clinical Thermometer * * * Cardinal Thermometer Co. 67–02 60th Street Brooklyn 27, N. Y."

RESULTS OF INVESTIGATION: Examination revealed that 7 out of 48 thermometers taken from this lot failed to comply with Commercial Standard CS1–52 since 5 failed to give readings of required accuracy and 2 failed to meet the hard shaker test.

LIBELED: 2–20–56, E. Dist. N. C.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statement in the labeling accompanying the article, when shipped, namely, "We, the undersigned manufacturers, hereby certify that this registering clinical thermometer has been tested and found to meet all the requirements and tests specified in Commercial Standard CS1–52, as developed by the trade under the procedure of the Commodity Standards Division, and issued by the United States Department of Commerce," was false and misleading.

DISPOSITION: 4–11–56. Default—destruction.

5069. Clinical thermometers. (F. D. C. No. 38987. S. No. 48–371 M.)

QUANTITY: 121 *clinical thermometers* at Passaic, N. J.

SHIPPED: 12–12–55, from New York, N. Y., by Emrose Thermometer Co.

LABEL IN PART: (Envelope) "Style Rectal One Omega Clinical Thermometer * * * Accurate."

RESULTS OF INVESTIGATION: Examination of 24 thermometers revealed that 6 thermometers failed to comply with the requirement for accuracy specified in CS1–52, issued by the National Bureau of Standards of the Department of Commerce, when tested as described in CS1–52.

LIBELED: 3–9–56, Dist. N. J.

CHARGE: 501 (c)—the quality of the article, when shipped, fell below that which it purported and was represented to possess; and 502 (a)—the statements in the labeling of the article, namely, (on certificate of examination) "We, the undersigned distributors hereby certify that this registering Clinical Thermometer marked OMEGA has been examined and tested and found to meet all the requirements and tests specified in commercial standard, CS1–52" and (on envelope and two-dozen package) "Accurate," were false and misleading since they were contrary to fact.

DISPOSITION: 4–24–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

5070. In-Flam-Go. (F. D. C. No. 33787. S. No. 31–615 L.)

INFORMATION FILED: 6–10–53, E. Dist. Mich., against Cripps In-Flam-Go Sales Co., a partnership, Detroit, Mich., and Keith J. Cripps, partner.

SHIPPED: 7–25–51, from Michigan to Missouri.

LABEL IN PART: (Btl.) "In-Flam-Go * * * Ingredients: Free Iodine and C. P. Oil."

ACCOMPANYING LABELING: Leaflets headed "It Will Surprise You" and "A Truly Remarkable Product" and a display easel headed "In-Flam-Go."

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for inflammation, goiter, varicose veins, sprains, arthritis, neuritis, sties, burns and scalds, underactive and overactive thyroid glands, neuralgia, backache, sore muscles, bruises, impetigo, varicose ulcers, gangrene, hardening of the arteries, tonsillitis, sore throat, ringworm, eczema, sinus conditions, swelling of the glands, and high blood pressure.

PLEA: Not guilty.

DISPOSITION: On 5–1–56, the case came on for trial before a court and jury. At the conclusion of the trial on 5–4–56, the court dismissed the case against the partnership, and the jury returned a verdict of guilty against Defendant Cripps. On 6–27–56, the court placed the defendant on probation for 2 years.

5071. Father Francis' herb formulas. (F. D. C. No. 37264. S. Nos. 82–922/30 L.)

INFORMATION FILED: 7–7–55, N. Dist. Ill., against Mary Piatek, t/a Father Francis' Herbs, Chicago, Ill.

ALLEGED VIOLATION: Between 11–11–53 and 10–5–54, the defendant caused a number of copies of a leaflet, which contained statements regarding the diseases, symptoms, and conditions for which the articles were intended, to accompany

*See also Nos. 5061, 5065, 5068, 5069.

the articles as labeling, which act resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

ACCOMPANYING LABELING: Leaflets entitled "From Nature's Own Laboratory . . . 'Nature—The Best Doctor.'"

RESULTS OF INVESTIGATION: The articles were designated as "Father Francis' Formula #1 [and "#2," "#3," "#4," "#5," "#6," "#7," "#8," and "#9."]."

CHARGE: 502 (a)—the accompanying labeling of the articles contained the following false and misleading representations:

That the *Formula #1* would be an adequate and effective treatment for conditions affecting the stomach and intestines, indigestion, hyperacidity, poisonous conditions of the intestines, colic, nausea, bloating, torpidity, headache, and insomnia;

That the *Formula #2* would be an adequate and effective treatment for liver and gallbladder troubles, impaired digestion, and impure intestinal tract;

That the *Formula #3* would be an adequate and effective treatment for diabetes;

That the *Formula #4* would be an adequate and effective treatment for kidney and bladder troubles, rheumatism, arthritis, internal pains, nervousness, sleeplessness, backache, swelling of ankles, puffiness under the eyes, loss of energy, loss of appetite, and lowered resistance against disease;

That the *Formula #5* would be an adequate and effective treatment for bronchitis, sore throat, and fever, and for preventing colds;

That the *Formula #6* would be an adequate and effective treatment for rheumatism, gout, arthritis, neuritis, sciatica, lumbago, and muscular chill;

That the *Formula #7* would be an adequate and effective treatment for nervousness, sleeplessness, weakened nerves, dizziness, heart trouble, palpitations of the heart, and breathlessness;

That the *Formula #8* would be an adequate and effective treatment for obesity and overweight troubles;

That the *Formula #9* would be an adequate and effective treatment for impaired circulation of the blood, impure skin, impaired metabolism, and impaired health.

PLEA: Not guilty.

DISPOSITION: 5–10–56. After a hearing in the matter, the court made a finding of guilty and imposed a fine of $50 on count 1 and $25 on each of counts 2 through 9. The fines on counts 2 through 9 were suspended, and the defendant was placed on probation for 5 years.

5072. Vin-Creo. (F. D. C. No. 37269. S. No. 5–496 M.)

INFORMATION FILED: 6–24–55, N. Dist. Ohio, against Vin-Creo Products, Inc., Cleveland, Ohio, and Dr. Abe A. Hopps, president of the corporation.

SHIPPED: 10–15–54, from Ohio to Michigan.

LABEL IN PART: (Btl.) "Vin-Creo 2 Oz. The Liquid Douche * * * Contents: Creosote Not Less Than ½ of 1%, Acetic Acid 4%, Glycerin 3%, Polysacchards 5 gm. d Fragrance Per Ounce."

ACCOMPANYING LABELING: Circulars entitled "Vin-Creo, The Liquid Douche" and form letters beginning with "Dear Madam."

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article would be adequate and effective for preventing "social disease" and venereal disease in the male and female;

for relieving pain and distressed feeling in the pelvic region, sick headache, backache, abdominal bloating, irritability, puffiness, cramps, premenstrual tension, and dysmenorrhea; for treating inflamed ovaries and tubes; for providing a protective film of antiseptic, germ-killing material over the cervix and the entire vaginal tract; and as a prophylactic against infection.

PLEA: Guilty by corporation and nolo contendere by Dr. Hopps.

DISPOSITION: 1–10–56, corporation fined $400; 6–22–56, Dr. Hopps placed on probation for 5 years.

5073. Salacetin Bell tablets and Sal Sperin Bell tablets. (F. D. C. No. 38397. S. Nos. 22–982 M, 22–985 M.)

QUANTITY: 11 btls. of *Salacetin Bell tablets* and 47 btls. of *Sal Sperin Bell tablets* at Boston, Mass.

SHIPPED: Between 2–18–55 and 5–13–55, from Orangeburg, N. Y., by Hollings-Smith Co., Inc.

LABEL IN PART: (Btl.) "One Hundred Tablets Six Grain Salacetin Bell C. P. Acetanilid 2.50 grs. per tablet with Sodium Salicylate and Sodium Bicarbonate" and "Seventy Tablets. Seven Grain Sal Sperin Bell (Improved) Calcium Gluconate Acetylsalicylic Acid (Aspirin) 3.5 gr."

ACCOMPANYING LABELING: Pamphlets entitled "Sal Sperin Bell For Arthritis—Rheumatism."

LIBELED: 8–19–55, Dist. Mass.

CHARGE: *Salacetin Bell tablets.* 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading statements relating to other drugs, *Sal Sperin Bell* and *Carbex Bell*, which statements represented and suggested that *Sal Sperin Bell* was an adequate and effective treatment for arthritis and rheumatism and that *Carbex Bell* was effective in irritative indigestions, severe and painful conditions, and for colic and bowel disturbances in infants and children.

Sal Sperin Bell tablets. 502 (a)—the accompanying labeling of the article, when shipped, contained false and misleading representations and suggestions that the article was an adequate and effective treatment for arthritis and rheumatism; the accompanying labeling contained also false and misleading statements relating to another drug, *Carbex Bell*, which statements represented and suggested that this product was effective in irritative indigestions, severe and painful conditions, and for colic and bowel disturbances in infants and children.

DISPOSITION: 2–6–56. Default—destruction. (6 btls. of *Salacetin Bell tablets* and 2 btls. of *Sal Sperin Bell tablets* actually were seized.)

5074. Tyrodine tablets. (F. D. C. No. 38412. S. No. 9–559 M.)

QUANTITY: 16,000 tablets in 100-tablet, 250-tablet, 500-tablet, and 1,000-tablet bottles at Los Angeles, Calif., in possession of Vitamin Quota.

SHIPPED: 4–1–55, from New York, N. Y.

LABEL IN PART: (Btl.) "Tyrodine Haynes Each tablet contains: 1-Tyrosine . . . 400 Mg. Vitamin B_6 (Pyridoxine Hydrochloride) . . . 2.5 Mg. Niacin Amide . . . 12.5 Mg."

RESULTS OF INVESTIGATION: The article had been shipped in bulk, and, upon receipt at Los Angeles, had been repackaged into bottles and relabeled by the consignee.

LIBELED: 9–1–55, S. Dist. Calif.

CHARGE: 502 (a)—the label of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for hay fever, bronchial asthma, food allergies, chronic eczemas, and chronic sinusitis, and that it was adequate and effective for the symptomatic relief of such conditions.

DISPOSITION: In accordance with a stipulation entered into between the government and Associated Laboratories, Inc., New York, N. Y., the claimant, an order was entered on 10–18–55 for the removal of the case to the E. Dist. N. Y. On 6–28–56, the claimant having withdrawn its claim, a default decree of condemnation and destruction was entered.

5075. Amosan tooth powder. (F. D. C. No. 39036. S. No. 23–983 M.)

QUANTITY: 12 cartons, 12 pkgs. each, at Los Angeles, Calif.

SHIPPED: 2–14–56 and 3–14–56, from Newark, N. J., by Knox Co.

LABEL IN PART: (Pkg.) "Amosan Powder * * * Active Ingredients: Sodium Perborate and Sodium Bitartrate, flavored with Oil of Peppermint and Menthol * * * Contains 20 Envelopes Net wt. 1¼ Avoir. Oz."

ACCOMPANYING LABELING: (Leaflet enclosed in each package) "Amosan Powder For the Hygienic Care of the Mouth and Gums."

LIBELED: 4–16–56, S. Dist. Calif.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for pyorrhea, trench mouth, and gingivitis.

DISPOSITION: 5–10–56. Default—destruction.

5076. Magnetic Ray device. (Inj. No. 19.)

APPLICATION FILED: On or about 7–22–44, in the Northern District of Texas, the United States attorney filed an application for an order which would require Frank B. Moran, t/a Magnetic Ray Co., Dallas, Tex., to show cause why he should not be punished for criminal contempt of the permanent injunction which had been entered against him on 6–30–42, as reported in notices of judgment on drugs and devices, No. 883.

CHARGE: It was alleged that the defendant, Frank B. Moran, had made a number of interstate shipments of the *Magnetic Ray device* in violation of the injunction.

DISPOSITION: An order to show cause was entered on 7–22–44, and in response thereto, an answer was filed by the defendant. The case came on for trial before the court without a jury on 8–10–44, and at its conclusion, the court handed down the following opinion, findings of fact, conclusions of law, and sentence:

ATWELL, *District Judge:* "On June 30, 1942, this injunction was granted under the statute. The Defendant, Frank B. Moran, individually and doing business as Magnetic Ray Company, and his agents, employees, representatives and all others acting by or under his direction and authority, and all persons, firms, partnerships, companies, corporations and their representatives, officers, servants, agents, employees in active concert or participating with defendant herein, be and are hereby perpetually enjoined and restrained from in any manner or by any device, directly or indirectly, further introducing or delivering for introduction into interstate commerce, or causing introduction or delivery for introduction into interstate commerce, of any device labeled 'Magnetic Appliance' or 'Magnetic Ray Instrument' or a similar device, similarly labeled in the manner and form of the aforesaid Magnetic Ray Instrument.

"From correspondence introduced at this trial the defendant represented that the injunction was a farce; it also shows that he sent a pamphlet out attacking the Court for issuing the restraint, and in the correspondence he advised that he appealed from that decision, and that it would be reversed, that the action of the court would be reversed. There was never any appeal from it, and he knew it. He knew very well that the injunction was against him, and the testimony shows here not only a contumacious attitude on the part of the defendant, but a determination to go forward with his business, and to carry it forward. He has been well represented at this trial, and guided in a manner that might have saved him from the predicament he is in if he had had that guidance at an earlier period.

"Assuming, without testimony, that the number of his so-called magnetic belts is as indicated by the number of those manufactured, and that he has gotten twenty dollars apiece for them, he would now have received $133,760.00 for the 6,688 of these so-called magnetic belts sold. The testimony does not show whether he started out with No. 1 or not, but it does show that No. 6688 has been introduced in interstate commerce. The lady testified, according to my recollection, substantially, that she made certain parts of this identical instrument. The testimony at the trial disclosed that a number of reputable physicians testified that the claim as to the curative powers of this so-called magnetic instrument were untrue. The Court, however, taking the side of the defendant, and not against the defendant, suggested that the Holy Writ was authority for the statement that if one believed he was healed, that he had the right to testify to such healing, and with that thought in mind, allowed the defendant to introduce his testimony, even though physicians testified that the instrument could not and would not do what the defendant claimed it would do. But one who is suffering from an ailment and comes up and says 'I am cured' certainly has the right to be heard, and the record in that case will show that the Court gave the defendant the benefit of that consideration.

"I am extremely careful in a contempt proceeding to discover contumacy, the determination to avoid and not follow the restraint issued by the Court, before punishment is inflicted. That appears here to be big, and this defendant has deliberately gone forward in his business without regard for the restraint, except to seek to cover up his actions by duplicity in a number of manners and matters, as best he could, to avoid discovery.

"Now there is this to be said for him: he is an elderly man, about seventy-nine years of age. The evidence does not disclose his pecuniary capacity, and I do not know whether he has funds to respond to a substantial fine or not, but this statute is a wholesome statute. I remember when it was placed on the books, and the paragraph to which Mr. McCutcheon now alludes with reference to where the Commissioner may issue a warning, has nothing to do with a case of this sort, as a reading of the statute will disclose. It does have a place in a certain part of the original investigation, but here is a remedy which was sought by the Government, and the Government secured the appropriate restraint at the hands of the Court and it must be obeyed. The punishment is in the hands of the Chancellor, who must be quick to discover that which is right and just, and I can hardly think of a more salutary road for the Government to travel than one which prevents the trusting to become the prey, if I may use that rather harsh word, of one who seeks funds. One of them is a man who comes and says he has gone into business with the instrument, himself limited apparently intellectually and perhaps in other ways, and he sends a check of rather good size for a sizeable order of the machines, and wrote that he could do a thriving business among the people in his section of the country, etc. It is unnecessary, I think, to go farther in that direction.

"I find as findings of fact:

"(1) That the defendant has violated the injunction.

"(2) That he knew he was violating the injunction, and did so on purpose.

"As a result of that, and as conclusions of law, I hold him guilty of contempt, and I fix his punishment at a fine of seven hundred and fifty dollars, and ten days in the county jail, the imprisonment to continue until the fine is paid.

"I have thought seriously about the costs the Government has been put to in this case. Witnesses who come from long distances cost money, and the defendant claims he was doing business from Maine to California, which challenges the Government in a sense. I believe in view of the fact that there is no disclosure of ability to respond, that this amount is rather substantial,

and that will be the judgment of the Court. Draw the Judgment, to be okayed by Mr. McCutcheon, saving such exceptions as may be desired, Mr. District Attorney."

5077. Magnetic Ray device. (Inj. No. 19.)

APPLICATION FILED: On or about 6–7–46, in the Northern District of Texas, the United States attorney filed an application for an order which would require Frank B. Moran, t/a Magnetic Ray Co., Dallas, Tex., to show cause why he should not be punished for criminal contempt of the permanent injunction which had been entered against him on 6–30–42, as reported in notices of judgment on drugs and devices, No. 883.

CHARGE: It was alleged that the defendant, Frank B. Moran, had made interstate shipments of the *Magnetic Ray device* on 1–29–45 and 2–19–45 in violation of the injunction.

DISPOSITION: 6–14–46. The defendant appeared before the court for a hearing, and at the conclusion thereof and after consideration of the pleadings and evidence and argument of counsel, the court found the defendant guilty of contempt and fined him $100, plus costs.

5078. Radioactive ore. (F. D. C. No. 37669. S. No. 16–098 M.)

QUANTITY: 6 100-lb. bags of *radioactive ore*, 105 9" by 12" canvas pads packed with *radioactive ore*, and 200 empty 9" by 12" canvas pads at Seattle, Wash., in possession of George Kosmos.

SHIPPED: On various dates during 1953, from McCall, Idaho.

LABEL IN PART: (Pad) "Cosmos Radioactive Pad."

ACCOMPANYING LABELING: Placards headed "The Radioactive Material in the Cosmos Radioactive Pad," "Arthritis? Bursitis?" and "Idaho Bursitis? Arthritis? Rheumatism? * * * Get the Cosmos Pad"; a copy of the 1–21–55 issue of Colliers Magazine; and 5 testimonial letters contained in a leather bound ring binder.

RESULTS OF INVESTIGATION: The *radioactive ore* had been shipped in bulk to Seattle, Wash., and upon its receipt by the consignee, a portion was repacked into the pads.

LIBELED: 2–24–55, W. Dist. Wash.

CHARGE: 502 (a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article would provide an adequate and effective treatment for arthritis, bursitis, rheumatism, neuritis, sinus trouble, and soreness of hands, wrists, forearms, and back.

DISPOSITION: 9–24–56. Consent—destruction.

DRUGS FOR VETERINARY USE

5079. Chick'n Tee. (F. D. C. No. 38738. S. No. 16–328 M.)

QUANTITY: 3 1-gal. btls., 45 1-qt. btls., 71 1-pt. btls., and 42 6-oz. btls. at Portland, Oreg.

SHIPPED: Between 10–3–55 and 12–9–55, from Omaha, Nebr., by Gland-O-Lac Co.

LABEL IN PART: (Btl.) "Gland-O-Lac * * * Chick'n Tee For The Drinking Water * * * Active Ingredient: Piperazine Hexahydrate. . . . 14.04% Inert Ingredients: Water and coloring. . . . 85.96%."

ACCOMPANYING LABELING: Leaflets entitled "Let Your Flock Drink the Worms Away Gland-O-Lac Chick'n Tee The New Liquid Poultry Wormer."

LIBELED: 2–3–56, Dist. Oreg.

CHARGE: 502 (a)—the labeling of the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for cecal worm infestation.

DISPOSITION: 4–10–56. Consent—claimed by Pat Nash Supply Co., Portland, Oreg., and relabeled.

5080. **Hydrozine.** (F. D. C. No. 38963. S. No. 11–693 M.)

QUANTITY: 14 27-oz. cans at Birmingham, Ala., in possession of Dorn & Mitchell Laboratories, Inc.

SHIPPED: 12–21–55, from Newark, N. J.

LABEL IN PART: (Can) "Hydrozine * * * Contents: Piperazine and stabilizers. Exclusive Distributors Dorn & Mitchell Laboratories Birmingham, Alabama."

RESULTS OF INVESTIGATION: The article was shipped in interstate commerce in bulk, and upon its receipt by the consignee, it was repackaged and relabeled.

LIBELED: 2–27–56, N. Dist. Ala.

CHARGE: 502 (a)—the labeling of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for all roundworms and cecal worms in poultry.

DISPOSITION: 3–27–56. Default—destruction.

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PRODUCTS

[1] (5065) Injunction issued.

[2] (5076) Contempt of injunction. Contains opinion of the court, findings of fact, conclusions of law, and sentence.

[3] (5077) Contempt of injunction.

[4] (5062, 5070, 5071) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5065) Injunction issued.
[4] (5062, 5070, 5071) Prosecution contested.

[2] (5076) Contempt of injunction. Contains opinion of the court, findings of fact, conclusions of law, and sentence.

[3] (5077) Contempt of injunction.

[4] (5062, 5070, 5071) Prosecution contested.

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U. S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

5081–5100

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503 (b) (1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 16, 1957.*

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447366—57

VIOLATIVE SALES OF PRESCRIPTION DRUGS

5081. (F. D. C. No. 36614. S. Nos. 33–514 L, 58–082 L, 58–808/9 L.)

INFORMATION FILED: 1–19–55, N. Dist. Ill., against **2600 State Drugs, Inc., Chicago, Ill., Edward Kravetz (vice president and manager of the drug department), Melburn Holtzman (secretary-treasurer and apprentice pharmacist), and Raymond Holtzman (clerk).**

CHARGE: Between 1–16–54 and 2–24–54, *amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed three times and *Sulfisoxazole tablets* (count 4) were dispensed once without a prescription.

DISPOSITION: On 3–14–55, the defendants filed a motion for dismissal of the information on the ground that the provisions of the Act which the defendants were charged to have violated were unconstitutional. This motion was denied by the court on 5–10–55. On 6–6–55, pleas of not guilty were entered by the corporation to all 4 counts of the information; by Edward Kravetz to counts 1 and 2; by Raymond Holtzman to count 3; and by Melburn Holtzman to count 4.

The case came on for trial before the court without a jury on 9–21–55 and was concluded on 10–3–55, with a verdict of guilty and the imposition of the following sentences by the court: $1,000 fine, plus costs, against the corporation; $500 fine and imprisonment of 3 months against Edward Kravetz; and $250 fine and imprisonment of 3 months against Raymond Holtzman and Melburn Holtzman.

On 10–13–55, a notice of appeal to the United States Court of Appeals for the Seventh Circuit was filed, and on 7–11–56, this court handed down the following opinion:

SWAIM, *Circuit Judge:* "The defendant, 2600 State Drugs, Inc., and the individual defendants, Edward Kravetz, Melburn Holtzman and Raymond Holtzman, all of whom were either officers or employees of the defendant drug corporation, were charged in a criminal information with having sold, without a prescription, certain drugs in violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. Section 301, *et seq.* In a trial before the District Court all of the defendants were found guilty of violating the Act.

"The principal question presented by this appeal is whether or not those sections of the Federal Food and Drug Act which prohibit the sale of dangerous drugs without a prescription are sufficiently definite to give reasonable notice to persons bounded by the proscriptions of the Act and subject to its penalties.

"The applicable parts of Section 331 of 21 U. S. C. A. provide:

> Prohibited acts—
> The following acts and the causing thereof are hereby prohibited:
>
> * * * * * * *
>
> (b) The adulteration or misbranding of any * * * drug * * * in interstate commerce.
>
> * * * * * * *
>
> (k) The adulteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or *the doing of any other act* with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded. [Our emphasis.]

Section 353 of 21 U. S. C. A., concerning prescriptions by physicians, prescription requirements and the misbranding of drugs, provides:

(b) (1) A drug intended for use by man which—

* * * * * * *

(B) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an effective application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug * * *. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

* * * * * * *

(4) A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription." * * *

Section 355 of 21 U. S. C. A., concerning new drugs and the necessity of effective application, provides:

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary [of Health, Education and Welfare] an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; * * * and (6) specimens of the labeling proposed to be used for such drug.

"At the beginning of the trial of this case the parties stipulated that the drugs which the defendants were accused of dispensing without a prescription were drugs within the meaning of 21 U. S. C. A. Section 353 (b) (1) (B), as amended, and which prior to January 16, 1954, were shipped in interstate commerce into the State of Illinois and were held in the manufacturer's original labeled bottle, the label upon which included the statement, 'Caution: Federal Law Prohibits Dispensing Without Prescription.'

"In this case the evidence in the record furnished a sufficient basis for the finding of the trial court that the drugs in question could be safely used only under the direction and supervision of a physician and that the defendants dispensed said drugs without prescriptions, as charged in the information.

"Although admitting that the drugs here in question had been shipped in interstate commerce, that the container carried a label stating that federal law prohibited the sale of the drugs without a prescription, and that there was sufficient evidence to support the trial court's findings that the defendants had made sales of such drugs without prescriptions, the defendants insist that the language of the statute is so vague, uncertain and indefinite as to fall short of the constitutional requirements of due process of law. On this point the defendants contend that the statute here in question is so vague and indefinite 'that men of common intelligence must necessarily guess at its meaning and differ as to its application,' and that, therefore, the statute is too vague, indefinite and ambiguous to constitute a legal basis for a criminal charge. We think the provisions of this Act are sufficiently definite to support a criminal charge for the violation of the Act.

"In *Boyce Motor Lines* v. *United States*, 342 U. S. 337, the Court was considering the validity of a regulation promulgated by the Interstate Commerce Commission which provided that drivers of motor vehicles transporting certain explosives and poisonous gases should 'avoid, so far as practicable, and where feasible, by prearrangement of routes, driving into or through congested thoroughfares, places where crowds are assembled, street car tracks, tunnels, viaducts, and dangerous crossings.' In its opinion in that case the Court said (page 340):

> A criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation. But few words possess the precision of mathematical symbols, most statutes must deal with untold and unforeseen variations in factual situations, and the practical necessities of discharging the business of government inevitably limit the specificity with which legislators can spell out prohibitions. Consequently, no more than a reasonable degree of certainty can be demanded. Nor is it unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line.

"In *Sproles* v. *Binford*, 286 U. S. 374, the Court was considering a Texas statute which prohibited the carriage of overweight and oversize loads by commercial carriers but which permitted the granting by the State Highway Department of permits, for ninety days, for the carrying of such loads 'as cannot be reasonably dismantled.' The statute provided further that these loads were to be carried 'by the shortest practicable route.' The Court there held (page 393) that the phrase, 'shortest practicable route,' was not an expression too vague to be understood. The Court explained:

> The requirement of reasonable certainty does not preclude the use of ordinary terms to express ideas which find adequate interpretation in common usage and understanding. [Citing authorities.] The use of common experience as a glossary is necessary to meet the practical demands of legislation. In this instance, to insist upon carriage by the shortest *possible* route, without taking the practicability of the route into consideration, would be but an arbitrary requirement, and the expression of that which otherwise would necessarily be implied, in order to make the provision workable, does not destroy it. 286 U. S. at page 393.

"Another factor which we must consider in the instant case is the fact that the provisions of the sections of the Act here under consideration were to bind *pharmacists* and to subject them to penalties in case of violations.

"To ship these drugs in interstate commerce it was necessary for the manufacturer to qualify them pursuant to the requirements of Section 355 of the Act. The drugs were qualified for interstate shipment on the condition that the container in which they were shipped bear a label which read, 'Caution: Federal law prohibits dispensing without prescription.' Section 331 (k) of the Act prohibited the removal of this label. The evidence here showed that when the sales of these drugs were made the label on the container was intact. It would seem clear that any pharmacist who sold these drugs without a prescription would necessarily know that he was violating the Food and Drug Act but that in order to make such sales the defendants were willing to defy the prohibitions of the Act.

"The defendants also insist that that part of Section 353 (b) (1) (C) of the Act which provides that 'The act of dispensing a drug contrary to the provisions of this paragraph [without the prescription of a physician] shall be deemed to be an act which results in the drug being misbranded while held for sale,' goes beyond the purpose of the Food and Drug Act, the sole purpose of which is to inform and so protect the ultimate consumer that he may be guarded against misrepresentation. The defendants say that the arbitrary extension of the meaning of the word 'misbranded' constitutes an unreasonable exercise of the commerce powers of Congress and violates the Fifth and Tenth Amendments of the Constitution of the United States. This contention we think is answered in *United States* v. *Carlisle* (No. 15898), 5 Cir., ——F. 2d——, which was decided May 31, 1956. The court in the *Carlisle* case pointed out that the Act sets out the only way the drugs there in question could be dispensed and then goes on to say that the act of dispensing the drugs contrary to the provisions of the Act shall be deemed to be an act which results in the drug being misbranded. The court there said (page 6 of the slip opinion):

> This established, by law in this section, there is required only resort to 21 U. S. C. 331 (k), which denounces the offense of misbranding, and to Sec. 333, which fixes the penalty for that offense.

The court concluded:

> * * * that the sections taken together have provided as clearly as though it had all been written out in the same section, that one dispensing drugs of the kind dealt with here, contrary to the provisions of Sec. 353 (b) (1) shall be guilty of, and subject to the punishment provided by law for, an act of misbranding.

The court there held (page 7 of the slip opinion):

> * * * that the use of the word "deemed" in the Act creates an irrebuttable presumption, a rule of substantive law, and that the doing of the prohibited act, dispensing the drugs * * * without the authorization of the prescriber, makes refilling misbranding and subjects the dispenser to the penalties provided for misbranding.

"The defendants also insist that the sales of these drugs without prescriptions constituted purely intrastate transactions, that these drugs did not remain a part of the stream of interstate commerce, and that the sales of the drugs at retail did not affect interstate commerce directly or indirectly. In support of this contention the defendants cite *Schechter Corp* v. *United States*, 295 U. S. 495, 544. But we think this contention is answered in *United States* v. *Sullivan*, 332 U. S. 689. In the latter case the defendant Sullivan, a retail druggist in Columbus, Georgia, purchased from a wholesale druggist in Atlanta, Georgia, a bottle of sulfathiazole tablets which had been shipped in interstate commerce from Chicago, Illinois. The label on the bottle which the defendant received gave adequate directions for the use of the tablets and adequate warning to protect the ultimate consumer from dangers incident to their use. The defendant removed some of the tablets from the original labeled bottle and placed them in a pill box labeled with the name of the drug but without adequate directions for use or warnings of danger. The Court there, after pointing out that the defendant had bought the drugs over six months after the interstate commerce shipment to the purchaser in Atlanta had been completed, said (pages 696 and 697):

> But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of section 301 (k) [section 331 (k) of the present Act].
>
> * * * The words of paragraph (k) "while such article held for sale after shipment in interstate commerce" apparently were designed to fill this gap [left by paragraphs (a), (b) and (c)] and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer.

In the *Sullivan* case the Court rejected the contention that its holding permitted Congress to invade the powers reserved by the Constitution to the states, pointing out that it had held in *McDermott* v. *Wisconsin*, 228 U. S. 115, that the authority of Congress to make such requirements was a proper exercise of its powers under the commerce clause.

"We think that the principles announced by the Court in the *Sullivan* and *McDermott* cases require us to hold here that Congress properly exercised its powers under the commerce clause by providing that drugs which have been transported in interstate commerce and which are dangerous to human beings unless their use is prescribed by a physician should not be dispensed except on the prescription of a physician.

"The judgment of the District Court is AFFIRMED."

A petition for a writ of certiorari was filed with the United States Supreme Court. On 10–8–56, the Supreme Court denied the petition.

5082. (F. D. C. No. 38533. S. Nos. 1–359 M, 1–712 M.)

INFORMATION FILED: 10–25–55, N. Dist. Ga., against **Max Freedman, t/a Sun Cut Rate Drugs, Atlanta, Ga.**

CHARGE: On or about 5–20–55, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 7–6–56. Defendant fined $100 and placed on probation for 1 year.

5083. (F. D. C. No. 38539. S. Nos. 22–259/60 M.)

INFORMATION FILED: 10–24–55, N. Dist. Ill., against **Adolph J. Waitkus, t/a Waitkus Pharmacy, Chicago Heights, Ill.**

CHARGE: 10–4–55 and 10–6–55, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–11–56. Defendant fined $2,000 and placed on probation for 3 years.

5084. (F. D. C. No. 38164. S. Nos. 834 M, 1–681 M, 1–685 M, 27–726 M.)

INFORMATION FILED: 10–25–55, S. Dist. Ga., against **Hugh Helmly, manager of A & M Truck Terminal, U. S. Highways 301 and 25, North of Claxton, Ga., and C. E. Hoots, an employee.**

CHARGE: Between 1–15–55 and 8–2–55, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Nolo contendere—by Hoots to counts 1 and 2 of the information and by Helmly to counts 3 and 4.

DISPOSITION: 2–13–56. Helmly fined $1,000 and placed on probation for 2 years; Hoots sentenced to imprisonment for 1 year and 1 day.

5085. (F. D. C. No. 38163. S. Nos. 1–760 M, 27–724/5 M.)

INFORMATION FILED: 10–25–55, N. Dist. Ga., against **George J. Johnson, Sr. (partner in Johnson's Truck Stop), Jonesboro, Ga., and George J. Johnson, Jr., and Mildred Sweatman (employees).**

CHARGE: Between 6–8–55 and 7–2–55, *amphetamine sulfate tablets* (counts 1, 2, and 3) were dispensed 3 times without a prescription.

PLEA: Guilty—by George J. Johnson, Sr., to count 3; by Mildred Sweatman to count 1; and by George J. Johnson, Jr., to all 3 counts of the information.

DISPOSITION: 7–27–56. George J. Johnson, Sr., and George J. Johnson, Jr., were fined $100 and placed on probation for 2 years; Mildred Sweatman was placed on probation for 2 years.

5086. (F. D. C. No. 37267. S. Nos. 90–346 L, 90–349 L.)

INFORMATION FILED: 6–28–55, Dist. Nebr., against **Louis J. Abramson (a partner in the Omaha Pharmacy), Omaha, Nebr.**

CHARGE: Between 9–29–54 and 10–5–54, *amphetamine sulfate tablets* were dispensed twice without a prescription.

DISPOSITION: In accordance with the defendant's motion, which was sustained by the court, a bill of particulars was filed by the Government on 8–15–55. On 9–8–55, the defendant entered a plea of not guilty, which was changed to

a plea of nolo contendere on 12–17–56. On 1–3–57, the court fined the defendant $200 plus costs.

5087. (F. D. C. No. 37265. S. Nos. 90–343 L, 90–345/6 L, 90–349/50 L, 90–450 L, 8–650 M.)

INFORMATION FILED: 6–30–55, Dist. Nebr., against **Allison J. Koory (also known as Abie Koory), t/a Koory Variety Store, Omaha, Nebr.**

CHARGE: Between 9–22–54 and 12–22–54, *amphetamine sulfate tablets* were dispensed 4 times and *pentobarbital sodium capsules* were dispensed 3 times without a prescription.

DISPOSITION: In accordance with the defendant's motion, which was sustained by the court, a bill of particulars was filed by the Government on 8–15–55. On 9–8–55, the defendant entered a plea of not guilty, which was changed to a plea of nolo contendere on 12–17–56. On 1–3–57, the court sentenced the defendant to 6 months in prison, which was suspended, and placed him on probation for 2 years.

5088. (F. D. C. No. 38592. S. Nos. 29–135 M, 29–556 M, 29–595 M.)

INFORMATION FILED: 3–14–56, Dist. N. J., against **Isadore Davis, t/a Sussex County Drug Co., Newton, N. J.**

CHARGE: Between 8–16–55 and 8–25–55, *Dexedrine Sulfate tablets* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once without a prescription, and *Butazolidin tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 5–1–56. $300 fine.

5089. (F. D. C. No. 38129. S. Nos. 470 M, 6–192 M.)

INFORMATION FILED: 7–2–56, S. Dist. Ind., against **Maynel W. Dalby, Sr., president of University Drug Store, Inc., Muncie, Ind.**

CHARGE: On 2–23–55, *Dexedrine Sulfate tablets* were dispensed once without a prescription, and *pentobarbital sodium capsules* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 8–10–56. $700 fine, plus costs.

5090. (F. D. C. No. 38511. S. Nos. 6–617/8 M, 19–241/2 M.)

INDICTMENT FILED: 12–12–55, N. Dist. Ohio, against **Prospect Drug Co., Inc., Cleveland, Ohio, and Samuel Grossman, president of the corporation.**

CHARGE: 3–11–55 and 3–15–55, *dextro-amphetamine sulfate tablets* and *pentobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 9–19–56. Suspended fine of $100 against corporation; individual sentenced to imprisonment for 181 days.

5091. (F. D. C. No. 37863. S. Nos. 10–790/2 M.)

INFORMATION FILED: 9–28–55, S. Dist. Tex., against **Thomas W. Cooper (pharmacist for O. S. T. Pharmacy, Inc.), Houston, Tex.**

CHARGE: Between 12–1–54 and 12–4–54, *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court without a jury on 11–15–55, and at its conclusion, the court found the defendant guilty. On 7–6–56, the court sentenced the defendant to 4 months in prison, but suspended this sentence, and placed him on probation for 2 years without supervision.

5092. (F. D. C. No. 38574. S. Nos. 35–901/6 M.)

INFORMATION FILED: 3–3–56, N. Dist. Ind., against **Hubert H. Fischer, t/a Fischer's Drug Store, Kendallville, Ind.**

CHARGE: Between 8–24–55 and 9–12–55, *Benzedrine Sulfate tablets* were dispensed 3 times, and *Gantrisin tablets, dextro-amphetamine sulfate tablets,* and *pentobarbital sodium capsules* were each dispensed once, without a prescription.

PLEA: Nolo contendere..

DISPOSITION: 6–25–56. $300 fine; jail sentence of 1 year on each of the 6 counts of the information suspended and defendant placed on probation for 5 years.

5093. (F. D. C. No. 38588. S. Nos. 37–220 M, 47–507 M, 47–520 M.)

INDICTMENT RETURNED: 2–16–56, Dist. N. J., against **Reginald Doyle Groves, t/a Groves Pharmacy, Newark, N. J.**

CHARGE: Between 12–5–55 and 1–9–56, *Benzedrine Sulfate tablets, Racephen tablets,* and *capsules containing a mixture of secobarbital sodium and amobarbital sodium* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 4–27–56. Defendant sentenced to serve 2 years in jail, given 3-year suspended jail sentence, and given 5 years' probation to start on completion of jail sentence.

5094. (F. D. C. No. 38578. S. Nos. 17–987 M, 17–997 M, 18–312 M.)

INFORMATION FILED: 2–23–56, Dist. N. J., against **Louis H. Fortgang, t/a Prebol Drug Co., Passaic, N. J.**

CHARGE: Between 5–13–55 and 5–24–55, *Seconal Sodium capsules* and *Butazolidin tablets* were each dispensed once upon requests for prescription refills without authorization by the prescribers, and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–10–56. $300 fine; jail sentence of 1 year suspended and defendant placed on probation for 1 year.

5095. (F. D. C. No. 38552. S. Nos. 2–864 M, 2–867 M, 2–872 M, 3–443 M, 3–449 M, 3–621 M, 3–652 M.)

INFORMATION FILED: 4–25–56, Dist. Mass., against **Phillips Drug Co., Inc., Boston, Mass., Charles C. Spagnolo (president), and Joseph Greenblatt (pharmacist).**

CHARGE: Between 3–8–55 and 4–6–55, *Seconal Sodium capsules* were dispensed 4 times, *Butazolidin tablets* were dispensed twice, and *Pentids tablets* were dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty.

DISPOSITION: 2–18–57. Fine of $500 against corporation, $300 against Spagnolo, and $200 against Greenblatt.

5096. (F. D. C. No. 36597. S. Nos. 82–156/8 L, 82–163/5 L.)

INDICTMENT RETURNED: 10–27–54, W. Dist. Mo., against **Black's Prescription Shop, Inc., Kansas City, Mo., Lorren R. Black (president), and Virgil L. Haag and George E. Nicholas (pharmacists).**

CHARGE: Between 2–10–54 and 3–4–54, *tablets containing a mixture of sulfadiazine, sulfamerazine, sulfamethazine, and penicillin G potassium* (counts 1, 2, and 3) and *tablets containing phenobarbital* as one of the ingredients (counts 4, 5, and 6) were each dispensed 3 times upon requests for prescription refills without authorization by the prescriber.

PLEA: Not guilty—by corporation and Black to all counts of the indictment; by Haag to counts 1 and 3; and by Nicholas to counts 4 and 6.

DISPOSITION: On 11–3–55, a motion for dismissal of the indictment as to Lorren R. Black was filed; on 11–22–55, the court entered the following order in denial of such motion:

DUNCAN, *Chief Judge:* "On October 27, 1954, the defendants were charged in six counts of an indictment with violating § 353 (b) (1) (B), Title 21 U. S. C. as amended. The first count of the indictment charges:

> That thereafter, on or about February 19, 1954, and while a number of tablets of said drug were being held for sale after shipment in interstate commerce, as aforesaid, at Black's Prescription Shop, Inc., 1125 Grand Avenue, Kansas City, Missouri, the said Black's Prescription Shop, Inc., a corporation, organized and existing under the laws of the State of Missouri, and trading and doing business at Kansas City, Missouri, and Lorren R. Black, at the times hereinbefore mentioned president and treasurer of said corporation, and Virgil L. Haag, an individual, at the times hereinbefore mentioned a pharmacist for said corporation, the *defendants* herein, did, at Kansas City, Missouri, within the Western Division of the Western District of Missouri, cause a number of tablets of said drug to be dispensed in a vial to one James R. Green, upon his request for a refill of a written prescription identified as No. 487494, without obtaining authorization by the prescriber.
>
> * * * * * * *
>
> That said act of causing the dispensing of said drug, as aforesaid, was an act caused to be done by said *defendants*, contrary to the provisions of 21 U. S. C. 353 (b) (1), which resulted in said drug in said vial being misbranded while held for sale, in violation of Title 21, United States Code, Section 331 (k). [Emphasis supplied.]

"The defendant Lorren R. Black has filed a Motion to Dismiss the indictment as to him. Accompanying the Motion to Dismiss is a stipulation which has been filed by the District Attorney and the attorney for the defendants, stipulating—

> That the defendant Lorren R. Black did not physically participate in any act charged to have been caused, done or performed by him, as alleged in Counts I to VI inclusive of the Indictment herein.

"Said defendant insists that in view of the stipulation that this defendant did not physically participate in any act charged, absolves him from all criminal responsibility in connection with the violation of the statute. The question has been passed on in *U. S.* v. *Dotterweich*, 320 U. S. 1. c. 281 in which the Court said:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.

"The fact that the defendant Black did not actually participate in the offense, would not absolve him from responsibility. Whether a lack of knowledge of it (which is not revealed here) would absolve him from responsibility is a matter which will have to be determined upon a trial of the case. The indictment charges an offense against said defendant. The stipulation, which says the act was not actually done or participated in by the said defendant, is not a defense under the statute.

"The Motion to Dismiss must therefore be, and is hereby, overruled."

The case came on for trial before the court without a jury on 3–13–56, and at the conclusion of the Government's evidence, the court granted a motion for the acquittal of Lorren R. Black. The other defendants rested their case without offering testimony and submitted motions for acquittal. The matter was taken under advisement by the court; and on 5–4–56, after consideration of the evidence and the briefs of counsel, the court found that the defendants, namely, Black's Prescription Shop, Inc., Virgil L. Haag, and George E. Nicholas, were not guilty as second offenders under the Act, as alleged in the indictment, since no evidence had been submitted to identify and prove that these defendants were second offenders. The court did find, however, that such defendants were guilty as first offenders with respect to the offenses charged and imposed a fine of $600 against the corporation, $200 against Virgil Haag, and $200 against George Nicholas.

5097. (F. D. C. No. 38591. S. Nos. 29–530 M, 30–010 M.)

INFORMATION FILED: 3–21–56, Dist. N. J., against **John J. Mayer, t/a Newton Drug Store, Newton, N. J.**

CHARGE: Between 8–18–55 and 8–31–55, *Bicillin tablets* were dispensed once without a prescription, and *Dexedrine Sulfate tablets* were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty.

DISPOSITION: 4–27–56. $200 fine.

5098. (F. D. C. No. 38557. S. Nos. 7–057 M, 7–061/2 M.)

INFORMATION FILED: 12–27–55, Dist. Colo., against **Kenneth H. Kimball and Donald E. Meyer (pharmacists for the Walgreen Drug Store, 235 16th Street, Denver, Colo.).**

CHARGE: Between 3–28–55 and 4–15–55, *thyroid tablets* (count 2) and *Dexedrine Sulfate tablets* (count 3) were each dispensed once without a prescription, and *cortisone acetate tablets* (count 1) were dispensed once upon request for a prescription refill without authorization by the prescriber.

PLEA: Guilty—by Kimball to count 1 and by Meyer to counts 2 and 3.

DISPOSITION: 5–18–56. Each defendant fined $100 and placed on probation for 6 months.

5099. (F. D. C. No. 38626. S. Nos. 42–456 M, 42–786 M.)

INFORMATION FILED: 8–18–56, N. Dist. Tex., against **Homer W. Nelson, t/a Nelson's Pharmacy, Brownfield, Tex., and Polly Porter Nelson (clerk.)**

CHARGE: Between 11–8–55 and 12–7–55, *Achromycin capsules* and *Neopenzine tablets* were each dispensed once without a prescription.

PLEA: Guilty—by Homer W. Nelson to dispensing *Achromycin capsules* and by Polly Porter Nelson to dispensing *Neopenzine tablets.*

DISPOSITION: 11–7–56. Homer Nelson fined $300 and placed on probation for 3 years; Polly Nelson fined $100 and placed on probation for 1 year.

5100. (F. D. C. No. 37260. S. Nos. 67–410/12 L.)

INFORMATION FILED: 1–24–57, N. Dist. Tex., against **Jack Aaron Bloom, t/a Dorchester House Pharmacy, Dallas, Tex.**

CHARGE: Between 3–27–54 and 4–13–54, *Two-Barbital capsules* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 1–24–57. Fine of $500 on count 1 to be paid immediately; fine of $500 on counts 2 and 3 to be probated 1 year.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 5081 TO 5100

PRODUCTS

[1] (5081) Prosecution contested. Contains opinion of the court.
[2] (5091) Prosecution contested.
[3] (5096) Prosecution contested. Contains order of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (5081) Prosecution contested. Contains opinion of the court.
[2] (5091) Prosecution contested.
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